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THALOMID[®] (thalidomide)

NDA # 020785

Celgene Corporation

86 Morris Avenue

Summit, NJ 07901

Contact Information:

1-908-673-9000

www.celgene.com

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

1. GOALS

The goals of the THALOMID risk evaluation and mitigation strategy are as follows:

1. To prevent the risk of embryo-fetal exposure to THALOMID.
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for THALOMID.

2. REMS ELEMENTS

2.1. Elements to Assure Safe Use

2.1.1. Healthcare providers who prescribe THALOMID are specially certified.

Celgene will ensure that healthcare providers who prescribe THALOMID are specially certified in the THALOMID REMS[™] program. THALOMID[®] (thalidomide) is available only through a restricted distribution program, THALOMID REMS[™].

To become certified, each prescriber must complete the Prescriber Enrollment Form and agree to do the following:

- a. Provide patient counseling on the benefits and risks of THALOMID therapy, including risks described in the BOXED WARNINGS.
- b. Enroll each patient by completing and submitting to the Celgene Customer Care Center via mail (86 Morris Avenue, Summit, NJ 07901), email (customer care@celgene.com), fax (1-888-432-9325), or online (www.celgeneriskmanagement.com), a signed Patient-Physician Agreement Form (PPAF) identifying the patient's risk category (see PPAFs) for all six risk categories) for each new patient. In signing the PPAF, each prescriber acknowledges that they understand that THALOMID is available only through the THALOMID REMS[™] program, and that they must comply with program requirements.

- c. Provide contraception and emergency contraception counseling with each new prescription prior to and during THALOMID treatment.
- d. Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions.
- e. Report any pregnancies in female patients or female partners of male patients prescribed THALOMID immediately to Celgene Drug Safety (or Celgene Customer Care Center (1-888-423-5436)).
- f. Complete a prescriber survey (phone or online) for every patient (new and follow-up), obtain a unique prescription authorization number for each prescription written, and include this authorization number on the prescription. The authorization number can be obtained by contacting the Celgene Customer Care Center, using the automated IVR system, or via the www.CelgeneRiskManagement.com website.
 - o For females of reproductive potential, authorization numbers are valid only for 7 days from date of last pregnancy test.
 - o Authorization numbers are valid for 30 days from the date it is issued for all other patients.
- g. Facilitate compliance with the mandatory THALOMID REMS™ patient survey by instructing patients to complete the mandatory surveys (phone or online) at program specified frequencies.
- h. Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions.
- i. Contact a pharmacy certified by the THALOMID REMS™ program to fill the THALOMID prescription.
- j. Return all unused THALOMID brought in by patients to Celgene Customer Care.
- k. Re-enroll patients in the THALOMID REMS™ program if THALOMID is required and previous therapy with THALOMID has been discontinued for 12 consecutive months.

Celgene will:

1. Ensure that the THALOMID REMS™ program materials including prescriber enrollment are available on the CelgeneRiskManagement.com website or can be obtained by contacting Celgene Customer Care Center at 1-888-423-5436
2. Maintain a secure database of all THALOMID REMS™ certified prescribers.
3. Monitor to ensure that only THALOMID REMS™ certified prescribers are prescribing THALOMID.
4. Monitor and ensure that patients have been assigned correctly to one of the following patient risk categories. Confirm risk category when completing the PPAFs during the patient enrollment process:
 - a. **Adult female of reproductive potential:** all females who are menstruating, amenorrheic from previous medical treatments, under 50 years, and/or perimenopausal.
 - b. **Female child of reproductive potential:** all females under 18 years who are menstruating.
 - c. **Adult female NOT of reproductive potential:** females who have had a natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy.
 - d. **Female child NOT of reproductive potential:** all females under 18 years who are not menstruating.
 - e. **Adult males 18 years or older**
 - f. **Male child under 18 years**
5. Monitor certified prescriber compliance with the THALOMID REMS™ program, including patient risk categorization and the appropriate corresponding counseling requirements, contraception requirements, pregnancy testing, and survey completion for all patients treated with THALOMID.

6. Institute corrective action and prevent the certified prescriber from prescribing THALOMID if the prescriber is found to be non-compliant with the THALOMID REMS™ program.
7. Train THALOMID REMS™ program certified prescribers in adverse experience reporting procedures, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to THALOMID if a pregnancy occurs
8. Ensure that once the prescriber submits the completed PPAF, the prescriber will receive a confirmation letter via fax or online to confirm the patient's enrollment and signify that the prescriber and patient surveys can be taken to receive an authorization number for the THALOMID prescription (for all males, the PPAF is considered the initial survey). The authorization number is written on the THALOMID prescription.
9. Ensure that, for subsequent prescriptions, the prescriber completes a telephone or online survey designed to look for signals of at-risk behavior (e.g., pending or outdated pregnancy test), report the patient's pregnancy test results, correct assignment of risk category, and confirm or re-enforce patient understanding of contraceptive requirements. The completion of the survey will allow the prescriber to obtain a new authorization number every time a prescription for THALOMID is written.

The following materials are part of the REMS, and are appended:

- [Prescriber Enrollment Form](#)
- [Patient Prescription Form](#)
- [Patient Prescription Form \(Veterans Administration\)](#)
- [Prescriber Guide to THALOMID REMS™ Program](#)
- [THALOMID REMS™ At-A-Glance](#)
- [Welcome Letter](#)
- [Celgene Risk Management.com website](#)

2.1.2. THALOMID will only be dispensed by pharmacies that are specially certified.

Celgene will ensure that THALOMID is only dispensed from THALOMID REMS™ program certified pharmacies. To become a THALOMID REMS™ program certified pharmacy, the pharmacy must agree to do the following before filling a THALOMID prescription:

- a. Only accept prescriptions with a prescription authorization number. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients.
- b. Dispense no more than a 4-week (28-day) supply, and require a new prescription from the patient prior to dispensing additional THALOMID.
- c. Dispense subsequent prescriptions only if there are 7 days or less remaining on an existing THALOMID prescription.
- d. Obtain a THALOMID REMS™ confirmation number from the Celgene Customer Care Center (phone or online) and write this confirmation number on the prescription. The THALOMID REMS™ confirmation number may be obtained using the following procedure:
 1. Enter the pharmacy identification number (NABP or DEA);
 2. Enter the prescription authorization number written on the prescription;
 3. Enter the number of capsules and milligram (mg) strength being dispensed;

4. Dispense or ship the prescribed THALOMID within 24 hours of obtaining and recording the THALOMID REMS™ confirmation number and confirmation date.
- e. Dispense THALOMID only after a THALOMID REMS™ confirmation number is obtained. If no confirmation is obtained, then no THALOMID is dispensed. Contact the patient's physician and Celgene for further instruction.
- f. Accept unused THALOMID (previously dispensed) from a patient or patient caregiver and return to Celgene Corporation for proper disposal.
- g. For each patient receiving treatment, retain a record of each THALOMID prescription dispensed and the corresponding completed Education and Counseling Checklist.
- h. Complete the checklist that applies to the patient risk category written on the front of the Education and Counseling Checklist for Pharmacies.
- i. Provide counseling to patients and/or guardians of patients under 18 years of age receiving THALOMID treatment.
 - a. Counsel all patients and guardians of patients under 18 years of age on the following:
 1. The benefits and risks of THALOMID therapy.
 2. Not sharing THALOMID medication.
 3. Not donating blood while taking THALOMID, during dose interruptions, and for 4 weeks after stopping THALOMID.
 4. Not to break, chew, or open THALOMID capsules.
 5. Instructions on THALOMID dose and administration.
 6. To read the THALOMID REMS™ program education materials and encourage compliance with the requirements.
 - b. In addition to above, counsel **Females of Reproductive Potential** on the following:
 1. The potential for embryo-fetal toxicity with exposure to THALOMID.
 2. Using 2 forms of effective birth control at the same time or abstaining from heterosexual sexual intercourse.
 3. Continuing to use 2 forms of birth control if THALOMID therapy is interrupted and for at least 4 weeks after therapy is discontinued.
 4. Obtaining a pregnancy test weekly during the first 4 weeks of THALOMID use, then a repeat pregnancy test every 4 weeks in females with regular menstrual cycles, and every 2 weeks in females with irregular menstrual cycles.
 5. The need to stop taking THALOMID and notify their THALOMID prescriber immediately if they become pregnant or suspect they may be pregnant.
 - c. In addition to items listed for all patients above, counsel **Males** receiving THALOMID treatment about the potential for embryo-fetal toxicity with exposure to THALOMID and the importance of using barrier contraception by wearing a latex or synthetic condom when engaging in sexual intercourse with a female of reproductive potential even if the male receiving THALOMID has had a successful vasectomy.
 1. The need to not donate sperm while taking THALOMID, during dose interruptions, and for 4 weeks after stopping THALOMID.
 - d. Counsel the **Parent or legal guardian of Female Child NOT of reproductive potential** who is receiving THALOMID treatment about the need to inform their THALOMID prescriber when the child begins menses.

Before a certified pharmacy dispenses THALOMID, Celgene will train the appropriate pharmacy staff:

1. About the THALOMID REMS™ program

2. About the procedures for reporting adverse experiences to Celgene, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to THALOMID if a pregnancy occurs.

The following materials are part of the REMS and are appended:

- [Pharmacy Guide to the THALOMID REMS™ Program](#)
- [Education and Counseling Checklist for Pharmacies](#)
- [Celgene REMS Programs Pharmacy Training: the THALOMID REMS™ Program](#)
- [Pharmacy Certification Quiz \(the THALOMID REMS™ Program\)](#)

2.1.3. Celgene will ensure that THALOMID will only be dispensed to patients enrolled in the THALOMID REMS™ program with evidence or other documentation of safe-use conditions.

Celgene will ensure that all patients treated with THALOMID are enrolled by a certified prescriber. The prescriber will enroll the patient by completing Patient-Physician Agreement Form and submitting the form via mail (86 Morris Avenue, Summit, NJ 07901), fax (1-888-432-9325), email (customer@celgene.com) or online (www.celgeneriskmanagement.com) for each patient who receives THALOMID. Each patient and/or guardian of patients under 18 years of age consents to participate in the program by:

- a. acknowledging that he or she understands that:
 - i. severe birth defects or death to an unborn baby may occur if a female becomes pregnant while she is receiving THALOMID;
 - ii. THALOMID must not be shared with anyone, even someone with similar symptoms;
 - iii. THALOMID must be kept out of the reach of children and should NEVER be shared with females who are able to have children;
 - iv. they cannot donate blood while receiving THALOMID, including dose interruptions, and for 4 weeks after stopping THALOMID;
 - v. they might be asked to participate in the THALOMID Pregnancy Exposure Registry; and
 - vi. they may be contacted by Celgene about following the rules of the REMS.
- b. In addition, each patient and/or guardian of patients under 18 years of age consents to participate in the program by:
 - i. agreeing to return unused THALOMID to Celgene or their THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to them;
 - ii. agreeing to participate in a monthly (telephone or online) survey while on THALOMID (with the exception of Adult Females Not of Reproductive Potential who are required to take a survey once every six months); and
 - iii. reviewing the THALOMID REMS™ program educational materials and asking their prescriber any questions that have not been answered.

In addition, **Females and guardians of female children** must attest to their understanding of their/their child's reproductive potential, as categorized by the prescribing physician.

Females of Reproductive Potential and guardians of Female Children of Reproductive Potential will attest that they/their child:

- a. is not currently pregnant, and will try to refrain from becoming pregnant while receiving THALOMID therapy and for at least 4 weeks after completely stopping THALOMID therapy;
- b. must not take THALOMID if pregnant, breastfeeding a baby, or not using birth control as defined in the REMS;
- c. will, unless abstinent, use contraception as defined within the REMS: for at least 4 weeks before starting THALOMID, while receiving THALOMID, during dose interruptions, and for at least 4 weeks after stopping THALOMID;
- d. will have pregnancy testing done as ordered by the certified prescriber within 10 to 14 days and 24 hours prior to starting THALOMID, every week for at least the first 4 weeks of THALOMID therapy, and then every 4 weeks if the Female of Reproductive Potential has regular menstrual cycles, or every 2 weeks if the Female of Reproductive Potential has irregular menstrual cycles, while receiving THALOMID;
- e. will immediately stop taking THALOMID and inform the certified prescriber if the patient becomes pregnant, misses a menstrual period, experiences unusual menstrual bleeding, stops using contraception, or thinks for any reason that she might be pregnant; if the prescriber is not available, the Female of Reproductive Potential or guardian of a Female Child of Reproductive Potential can call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information on emergency contraception.

Males or guardians of Males will attest that they/their child will:

- a. never have unprotected sexual contact with a female who can become pregnant;
- b. wear a latex or synthetic condom every time the male patient has sexual contact with a female who is or who can become pregnant; continue condom use with sexual contact while the male patient is receiving THALOMID treatment, during dose interruptions, and for 4 weeks after the male patient stops taking THALOMID, even if the patient has had a successful vasectomy; and
- c. inform their certified prescriber if the male patient has unprotected sexual contact with a female who can become pregnant, or if they think for any reason that the male patient's sexual partner might be pregnant; the male patient or guardian of an underage male patient can call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information on emergency contraception;
- d. not donate sperm while taking (including dose interruptions) and for 4 weeks after stopping THALOMID.

The following appended materials are part of the REMS:

- [Patient-Physician Agreement Form for Adult Male](#)
- [Patient-Physician Agreement Form for Male Child](#)
- [Patient-Physician Agreement Form Adult Female Who Can Not Get Pregnant](#)
- [Patient-Physician Agreement Form Adult Female Who Can Get Pregnant](#)
- [Patient-Physician Agreement Form Female Child Who Can Not Get Pregnant](#)
- [Patient-Physician Agreement Form Female Child Who Can Get Pregnant](#)
- [Patient Guide to THALOMID REMS™ Program](#)
- [Emergency Contraception Brochure](#)
- [Patient Survey Reminder Card](#)

- THALOMID Risk Evaluation and Mitigation Strategy (REMS)TM Program Education and Prescribing Safety Kit
- THALOMID REMSTM Patient Resource Pack Envelope

2.1.4 Female patients or female partners of male patients receiving THALOMID who report a pregnancy that occurred during THALOMID therapy will be enrolled in the THALOMID Pregnancy Exposure Registry. The registry will collect the following information:

Upon receiving a report of pregnancy from the THALOMID REMSTM program, Celgene Pregnancy Prevention Plan programs in the rest of the world, clinical trials, or directly from a prescriber, a pharmacy, or a patient, Celgene will enroll the female patient or female partner of the male patient taking THALOMID into the THALOMID Pregnancy Exposure Registry. The objectives of the registry are to monitor pregnancy outcomes in female patients of reproductive potential and male patients' female partners who are exposed to THALOMID and to understand why the THALOMID REMSTM program was unsuccessful.

2.2. Implementation System

The implementation system will include the following:

- 1) Celgene will maintain a secure database of all certified entities, including enrolled patients and certified prescribers and pharmacies to monitor and evaluate implementation of the elements provided for in Sections 2.1.1, 2.1.2, and 2.1.3.
- 2) Celgene will monitor THALOMID REMSTM program pharmacy certification compliance and address deviations by monitoring real time dispensing activity and conducting pharmacy audits.
 - a. The Celgene Customer Care Center will monitor the certified pharmacies in the manner described in the REMS supporting document to ensure only enrolled and authorized patients are receiving THALOMID. If a certified pharmacy is found to be non-compliant with the THALOMID REMSTM program, Celgene will institute corrective action and may de-activate pharmacies for which re-training has proven ineffective, removing them from the THALOMID REMSTM program.
 - b. Celgene will perform regular audits of contract pharmacies participating in the THALOMID REMSTM program. For pharmacies that have been in the program for more than two years, Celgene will perform a risk-based assessment to select which pharmacies will be audited. The THALOMID REMSTM program compliance audits will be performed by internal auditors of Celgene and/or outside auditors contracted and trained by Celgene.
- 3) Celgene will monitor and ensure that the prescriptions are filled within the allowed timeframes.
- 4) Celgene Customer Care Center will address customer complaints received that are related to the THALOMID REMSTM program and distribution and dispensing of THALOMID.
- 5) Celgene will maintain a reporting and collection system for safety information that includes a process to monitor pregnancy testing results and pregnancy outcomes (should one occur) through the THALOMID Pregnancy Exposure Registry and to understand why the THALOMID REMSTM program was unsuccessful for the pregnancy case in question.

- 6) Based on monitoring and evaluation of these elements to assure safe use, Celgene will take reasonable steps to work to improve implementation of these elements as applicable.
- 7) Celgene will develop and follow written procedures related to the implementation of the REMS.

2.3. Timetable for Submission of Assessment Reports

REMS assessments (THALOMID REMSTM update reports) will be submitted at 1 year, 2 years, then every 3 years thereafter from the date of the initial approval of the REMS (August 3rd, 2010). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment will conclude no earlier than 60 days before the submission date for that assessment. Celgene will submit each assessment so it will be received by the FDA on or before the due date.

THALOMID® (thalidomide) Patient Prescription Form

Today's Date _____ Date Rx Needed _____

Patient Last Name _____ Patient First Name _____

Phone Number () _____

Shipping Address _____

City _____ State _____

Zip _____

Date of Birth _____ Patient ID# _____

Language Preference: ☐ English ☐ Spanish
☐ Other _____

Best Time to Call Patient: ☐ AM _____ ☐ PM _____

Patient Diagnosis (ICD-10 Code) _____

Patient Allergies _____

Other Current Medications _____

Prescriber Name _____

State License Number _____

Prescriber Phone Number () _____

Fax Number () _____

Prescriber Address _____

City _____ State _____ Zip _____

Patient Type From PPAF (Check one)

- ☐ Adult Female – NOT of Reproductive Potential
- ☐ Adult Female – Reproductive Potential
- ☐ Adult Male
- ☐ Female Child – Not of Reproductive Potential
- ☐ Female Child – Reproductive Potential
- ☐ Male Child

PRESCRIPTION INSURANCE INFORMATION

(Fill out entirely and fax a copy of patient's insurance card, both sides)

Primary Insurance _____

Insured _____

Policy # _____

Group # _____

Phone # _____

Rx Drug Card # _____

Secondary Insurance _____

Insured _____

Policy # _____

Group # _____

Phone # _____

Rx Drug Card # _____

For further information on THALOMID, please refer to the full Prescribing Information

TAPE PRESCRIPTION HERE PRIOR TO FAXING REFERRAL, OR COMPLETE THE FOLLOWING:

Recommended Starting Dose: See below for dosage

Multiple Myeloma: The recommended starting dose of THALOMID is 200 mg/day orally with water for a 28-day treatment cycle. Dosing is continued or modified based upon clinical and laboratory findings.

Erythema Nodosum Leprosus: The recommended starting dose of THALOMID is 100 to 300 mg/day with water for an episode of cutaneous ENL. Up to 400 mg/day for severe cutaneous ENL. Dosing is continued or modified based upon clinical and laboratory findings.

THALOMID

Dose	Quantity	Directions
<input type="checkbox"/> 50 mg	_____	_____
<input type="checkbox"/> 100 mg	_____	_____
<input type="checkbox"/> 150 mg	_____	_____
<input type="checkbox"/> 200 mg	_____	_____

☐ Dispense as Written ☐ Substitution Permitted

NO REFILLS ALLOWED (Maximum Quantity = 28 days)

Prescriber Signature _____ Date _____

Authorization # _____ Date _____

(To be filled in by healthcare provider)

Pharmacy Confirmation # _____ Date _____

(To be filled in by pharmacy)

How to Fill a THALOMID® (thalidomide) Prescription

1. Healthcare provider (HCP) instructs female patients to complete initial patient survey
2. HCP completes survey
3. HCP completes patient prescription form
4. HCP obtains THALOMID REMS™ (formerly known as the S.T.E.P.S.® program) authorization number
5. HCP provides authorization number on patient prescription form
6. HCP faxes form, including prescription, to one of the Celgene Certified Pharmacy Network participants (see below)
7. HCP advises patient that a representative from the certified pharmacy will contact them
8. Certified pharmacy conducts patient education
9. Certified pharmacy obtains confirmation number
10. Certified pharmacy ships THALOMID to patient with MEDICATION GUIDE

Please see www.Celgene.com/PharmacyNetwork for the list of pharmacy participants

Information about THALOMID and the THALOMID REMS™ program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.CelgeneRiskManagement.com.



THALOMID® is a registered trademark of Celgene Corporation. THALOMID REMS™ is a trademark of Celgene Corporation.

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REMS-THA13242

THALOMID[®] (thalidomide) Patient Prescription Form – Veterans Administration (VA) ONLY

Today's Date _____ Date Rx Needed _____

Patient Last Name _____ Patient First Name _____

Phone Number () _____

Shipping Address _____

City _____ State _____ Zip _____

Date of Birth _____ Patient ID# _____

Language Preference: ☐ English ☐ Spanish

☐ Other _____

Best Time to Call Patient: ☐ AM _____ ☐ PM _____

Patient Diagnosis (ICD-10 Code) _____

Patient Allergies _____

Other Current Medications _____

Prescriber Name _____

State License Number _____

Prescriber Phone Number () _____ Ext. _____

Fax Number () _____

Prescriber Address _____

City _____ State _____ Zip _____

Patient Type From PPAF (Check one)

☐ Adult Female – NOT of Reproductive Potential

☐ Adult Female – Reproductive Potential

☐ Adult Male

☐ Female Child – Not of Reproductive Potential

☐ Female Child – Reproductive Potential

☐ Male Child

VA Pharmacy Information (Fill out entirely)

VA Name _____

Address _____

City _____ State _____ Zip _____

VA Pharmacist Name _____

Phone # _____ Fax # _____

McKesson Specialty Distribution Account # _____

Shipping Information

Check below for direct delivery to patient. If any information is omitted, product will be shipped to the VA Pharmacy.

☐ Patient Name _____

Address _____

City _____ State _____

Zip _____

Phone _____

For further information on THALOMID, please refer to the full Prescribing Information

TAPE PRESCRIPTION HERE PRIOR TO FAXING

REFERRAL, OR COMPLETE THE FOLLOWING:

Recommended Starting Dose: See below for dosage

Multiple Myeloma: The recommended starting dose of THALOMID is 200 mg/day orally with water for a 28-day treatment cycle. Dosing is continued or modified based upon clinical and laboratory findings.

Erythema Nodosum Leprosum: The recommended starting dose of THALOMID is 100 to 300 mg/day with water for an episode of cutaneous ENL. Up to 400 mg/day for severe cutaneous ENL. Dosing is continued or modified based upon clinical and laboratory findings.

THALOMID

Dose	Quantity	Directions
<input type="checkbox"/> 50 mg	_____	_____
<input type="checkbox"/> 100 mg	_____	_____
<input type="checkbox"/> 150 mg	_____	_____
<input type="checkbox"/> 200 mg	_____	_____

☐ Dispense as Written ☐ Substitution Permitted

NO REFILLS ALLOWED (Maximum Quantity = 28 days)

Prescriber Signature _____ Date _____

Authorization # _____ Date _____

(To be filled in by healthcare provider)

Pharmacy Confirmation # _____ Date _____

How to Fill a THALOMID[®] (thalidomide) Prescription in the Veterans Administration (VA)

1. Healthcare Provider (HCP) instructs female patients to complete initial patient survey
2. HCP completes survey
3. HCP completes patient prescription form (include cell number for patient if possible)
4. HCP obtains THALOMID REMS[™] (formerly known as the *S.T.E.P.S.*[®] program) authorization number
5. HCP provides authorization number on patient prescription form
6. HCP sends prescription to the VA Pharmacy

The following information must be filled in:

- Rx must include McKesson Specialty Distribution account number
- Rx must include VA address (Name, Street, City, State, ZIP)
- Rx must include VA Pharmacist contact information (Name, Phone and Fax #)

7. VA Pharmacist faxes the form, including prescription, to:

The THALOMID REMS[™] certified OncologyRx Care Advantage Specialty at 1-855-637-9446

8. HCP advises patient that a representative from THALOMID REMS[™] certified pharmacy will be in contact
9. The THALOMID REMS[™] certified OncologyRx Care Advantage Pharmacist conducts patient education
10. The THALOMID REMS[™] certified OncologyRx Care Advantage Pharmacist obtains confirmation number
11. The THALOMID REMS[™] certified OncologyRx Care Advantage Pharmacist ships THALOMID to the VA Pharmacy or directly to the patient with MEDICATION GUIDE
12. VA Pharmacist gives THALOMID to VA patient with MEDICATION GUIDE

THALOMID REMS[™] Veterans Administration (VA) Pharmacy OncologyRx Care Advantage

Phone: 1-855-637-9433 Fax: 1-855-637-9446

Information about THALOMID and the THALOMID REMS[™] program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.CelgeneRiskManagement.com.

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Prescriber Guide to

((THALOMID REMS™ logo))

Risk Evaluation and Mitigation Strategy (REMS)™ Program

A known teratogen, THALOMID® (thalidomide) is approved for marketing only under a restricted distribution program approved by the Food and Drug Administration. This program is called the THALOMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the *S.T.E.P.S.*® program).

This guide contains important information for prescribers about:

- The risks of THALOMID, including a boxed warning for
 - Embryo-fetal toxicity
 - Venous thromboembolism (deep venous thrombosis [DVT] and pulmonary embolism [PE])
- The THALOMID REMS™ program
 - Prescriber Certification
 - Patient Enrollment
 - Contraceptive Requirements and Counseling for Patients
 - Initial and Subsequent Prescription Requirements

THALOMID REMS™ Resources for Prescribers Include:

- Prescriber Guide to THALOMID REMS™ Program
- CD-ROM, including Patient-Physician Agreement Form and Patient Prescription Form Software and Installation Instructions
- Full Prescribing Information for THALOMID

((THALOMID logo))

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About THALOMID[®] (thalidomide)

THALOMID in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

Risks of THALOMID

THALOMID has a Boxed Warning for embryo-fetal toxicity and venous thromboembolism (deep venous thrombosis [DVT] and pulmonary embolism [PE]).

A known teratogen, THALOMID is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID if they take adequate precautions to avoid pregnancy.

The use of THALOMID in MM results in an increased risk of venous thromboembolism, such as deep venous thrombosis and pulmonary embolism. This risk increases significantly when THALOMID is used in combination with standard chemotherapeutic agents including dexamethasone. Patients and physicians should be observant for the signs and symptoms of thromboembolism. Instruct patients to seek medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Consider thromboprophylaxis based on an assessment of individual patients' underlying risk factors.

The THALOMID REMS™ program

To avoid embryo-fetal exposure, THALOMID® (thalidomide) is only available under a restricted distribution program called “THALOMID Risk Evaluation and Mitigation Strategy (REMS)™.” Only certified prescribers can prescribe THALOMID and only certified pharmacies can dispense THALOMID in the THALOMID REMS™ program.

In order to receive THALOMID, all patients must be enrolled in THALOMID REMS™ and agree to comply with the requirements of the THALOMID REMS™ program. Information about THALOMID and the THALOMID REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**.

Key points of the THALOMID REMS™ program

Prescriber

- The prescriber enrolls and becomes certified with Celgene for the THALOMID REMS™ program
- The prescriber counsels patient on benefits and risks of THALOMID
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a THALOMID® (thalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends THALOMID prescription to certified pharmacy

Pharmacy

- The pharmacy certifies with Celgene for THALOMID REMS™
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy dispenses THALOMID to patient along with a Medication Guide

THALOMID REMS™ patient enrollment

- Obtain, review, and complete the THALOMID® (thalidomide) Patient-Physician Agreement Form online at **www.CelgeneRiskManagement.com**, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**
- Prescribers who do not have access to a computer, or whose computer systems are not compatible with the software, will be provided with THALOMID REMS™ program materials. For additional assistance, please contact the Celgene Customer Care Center or your Celgene Hematology Oncology Consultant
- Patient, parent/legal guardian, and/or authorized representative must read the THALOMID® (thalidomide) Patient-Physician Agreement Form in the language of their choice

Help Ensure Timely Processing of Each Prescription

Fill Out Form as Directed

- Write only in the designated areas on the THALOMID® (thalidomide) Patient-Physician Agreement Form
- The box next to each statement must be marked (with an “X”) to indicate understanding
- The form must be completed and signed by both prescriber and patient

Instructions for Female Patients

- For female patients, the prescriber will need to provide information on whether the patient has been in surgical menopause, chemical menopause, or natural menopause for at least 24 months

Instructions for Minors

- If the patient is under 18 years of age, his or her legal guardian must read this material, mark the statement in each block of the form (with an “X”) and agree to ensure compliance by signing and dating the form

Instructions for Incompetent Adult Patients

- For an incompetent adult patient, an authorized representative must sign the THALOMID® (thalidomide) Patient-Physician Agreement Form
- An authorized representative is a caretaker authorized under applicable state law to consent to treatment on the incompetent patient’s behalf

THALOMID REMS™ patient enrollment (continued)

- The authorized representative must read the material, mark the statements, and agree to ensure compliance by signing and dating the form
- If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the THALOMID® (thalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the THALOMID® (thalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the THALOMID REMS™ program and is authorized to consent to treatment with THALOMID on behalf of the patient

Send in Completed Forms

- Send the completed THALOMID® (thalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**
- You will receive confirmation electronically or via fax to your office once the patient is enrolled
- Once the THALOMID® (thalidomide) Patient-Physician Agreement Form is received, both female patients and prescriber can take their surveys as required. Male patients do not take initial surveys
- In the event that you do not receive this confirmation within 15 minutes, call the Celgene Customer Care Center

Note: If therapy with THALOMID is discontinued for 12 consecutive months, the patient must enroll again in the THALOMID REMS™ program. Follow the above procedures to re-enroll the patient.

Initial prescription requirements

ALL PATIENTS

- Provide comprehensive counseling on the benefits and risks of therapy with THALOMID® (thalidomide)
- Patients must be counseled on the risks of birth defects, venous thromboembolism, other side effects, and important precautions associated with THALOMID
- Provide counseling not to share THALOMID capsules, and not to donate blood during treatment (including dose interruptions) and for 4 weeks after receiving their last dose of THALOMID, as well as counseling on appropriate contraceptive use, including emergency contraception
- Provide patients with education materials provided in the THALOMID REMS™ Patient Resource Pack
- Patients should be instructed to not extensively handle or open THALOMID capsules and to maintain storage of capsules in blister packs until ingestion
- Instruct patients to return unused THALOMID capsules for disposal to Celgene or to their THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to them

FEMALE PATIENTS

Determine if female patient is of reproductive potential

Two categories:	
1.	Females of Reproductive Potential <ul style="list-style-type: none">• All females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category
2.	Females Not of Reproductive Potential <ul style="list-style-type: none">• Females who have been in natural menopause for at least 24 consecutive months, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating

Initial prescription requirements (continued)

1. Females of Reproductive Potential

Pregnancy test requirements

- Obtain a **negative** pregnancy test 10 to 14 days prior to writing an initial prescription for THALOMID® (thalidomide) and again within 24 hours prior to writing an initial prescription for THALOMID even if continuous abstinence is the chosen method of birth control
 - The pregnancy test must be sensitive to at least 50 mIU/mL
 - Pregnancy testing should occur weekly during the first 4 weeks of use
 - Pregnancy testing should be repeated every 4 weeks if patient has regular menses or is amenorrheic, or every 2 weeks if irregular menses
 - If a patient misses her period or if there is any abnormality in menstrual bleeding, THALOMID should be discontinued immediately. Obtain a pregnancy test and counsel the patient
- **If pregnancy does occur during treatment, THALOMID must be immediately discontinued.** Any suspected embryo-fetal exposure to THALOMID must be reported immediately to the FDA via the MedWatch number at **1-800-332-1088** and also to the Celgene Customer Care Center at **1-888-423-5436**. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling
- The patient must not breastfeed a baby while being treated with THALOMID

Initial prescription requirements (continued)

Patient Counseling on Contraception Requirements

Contraception requirements

- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include using at the same time at least 1 highly effective method and at least 1 additional method of birth control every time they have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before THALOMID® (thalidomide) therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

Effective Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Male latex or synthetic condom
Tubal ligation (having your tubes tied)	Diaphragm
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	Cervical cap

Remind all patients that not having any sexual intercourse is the only birth control method that is 100% effective.

- **Unacceptable forms of contraception:**

- Progesterone-only “mini-pills”
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield*

- Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the effects of hormonal contraception. If hormonal or IUD contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after

*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

Initial prescription requirements (continued)

2. Females Not of Reproductive Potential

- The patient must confirm that she is currently not pregnant, nor of reproductive potential as she has been in natural menopause for at least 24 months, or had a hysterectomy and/or bilateral oophorectomy
- The parent or guardian must confirm that a prepubertal female child is not now pregnant, nor is of reproductive potential as **menstruation has not yet begun**, and/or the child will not be engaging in heterosexual sexual contact for at least 4 weeks before THALOMID® (thalidomide) therapy, during therapy, and for at least 4 weeks after stopping therapy

MALE PATIENTS

- Male patients must be instructed to use a latex or synthetic condom every time they have sexual intercourse with a female of reproductive potential, even if they have undergone a successful vasectomy. The risk to the developing baby from the semen of male patients taking THALOMID is unknown
- Male patients must be instructed not to donate sperm during treatment (including dose interruptions) and for 4 weeks after their last dose of THALOMID

Initial mandatory confidential survey

Females

- Instruct the female patient to complete a brief initial mandatory confidential survey at **www.CelgeneRiskManagement.com**, or by calling **1-888-423-5436**. See page 12 for subsequent prescription requirements

Males

- Males do not need to take the initial survey

Prescribers

- Prescriber will complete a brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or by calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written. Be prepared to enter some of the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supply (cannot exceed 28 days)
- An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted

ADDITIONAL INFORMATION FOR THE PRESCRIBER

- Healthcare provider must send the prescription to a THALOMID REMS™ certified pharmacy. To locate a certified pharmacy, please visit **www.Celgene.com/PharmacyNetwork**
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills

Subsequent prescription requirements

The prescriber must complete a brief mandatory confidential survey to obtain a new authorization number **every time** a prescription for THALOMID® (thalidomide) is written.

No automatic refills or telephone prescriptions are permitted. The patient risk category must be written on the prescription.

FEMALE PATIENTS

- Provide counseling as outlined in the “FEMALE PATIENTS” section on pages 7-10
- Follow pregnancy test requirements as outlined in “Pregnancy test requirements” section on page 8
- Female patients must complete a brief mandatory confidential survey according to the following schedule:
 - Before prescription is obtained
 - Monthly
 - Adult females of reproductive potential
 - All female children
 - Every 6 months
 - Adult females not of reproductive potential

MALE PATIENTS

- Provide patient counseling as outlined in the “MALE PATIENTS” section on page 10
- Male patients must complete a brief mandatory confidential survey once a month
 - Males do not complete an initial survey

After the last dose of THALOMID[®] (thalidomide)

After patients have stopped taking THALOMID, they must do the following:

ALL PATIENTS

- Must not share THALOMID capsules—especially with females of reproductive potential
- Must return any unused THALOMID capsules for disposal to Celgene or their THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to them
- Must not donate blood for 4 weeks after stopping THALOMID

FEMALE PATIENTS

- Must not get pregnant for at least 4 weeks after stopping THALOMID by using the appropriate contraceptives each time engaging in sexual activity with a male

MALE PATIENTS

- Must use a latex or synthetic condom for 4 weeks after stopping THALOMID
- Must not donate sperm for 4 weeks after stopping THALOMID

Ordering English and non-English materials

CALL CELGENE CUSTOMER CARE CENTER AT 1-888-423-5436

- Materials are available in 16 languages and include:
 - THALOMID® (thalidomide) Patient-Physician Agreement Forms
 - Patient Guide to THALOMID REMS™ Program
 - Mandatory confidential survey forms

Available languages:

Arabic	French	Japanese	Portuguese
Cambodian	German	Korean	Russian
Chinese	Greek	Laotian	Spanish
English	Italian	Polish	Vietnamese

- THALOMID® (thalidomide) Patient-Physician Agreement Forms, Patient Guide to THALOMID REMS™ Program, and mandatory confidential survey forms requested will be faxed directly to the number you indicate. Please be prepared to provide:

Prescriber's:

Name

Identification Number

Full Address

Fax Number

Patient's:

Name

Full Address

Phone Number

Date of Birth

Identification Number

Diagnosis (most recent version of ICD code)

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of THALOMID® (thalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID to Celgene using any of the following methods.

REPORTING TO CELGENE

- Email: **drugsafety@celgene.com**
- Telephone: **1-908-673-9667**
- Toll-free: **1-800-640-7854** (Global Drug Safety & Risk Management) or **1-888-423-5436** (Celgene Customer Care Center)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online: **<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>**
- Telephone: **1-800-332-1088**
- Fax: **1-800-332-0178**
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

[Back Cover]

For more information about THALOMID[®] (thalidomide) and the THALOMID REMS[™] program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation

86 Morris Ave

Summit, NJ 07901

THALOMID is only available under a restricted distribution program, THALOMID REMS[™].

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo))
((THALOMID logo))

((THALOMID REMS[™] logo))

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THALOMID REMS™

At-A-Glance

Important information about THALOMID® (thalidomide) and the THALOMID Risk Evaluation and Mitigation Strategy (REMS)™ program

- THALOMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called “THALOMID REMS™” (formerly known as the *S.T.E.P.S.*® program)
- Only prescribers and pharmacies certified by the THALOMID REMS™ program can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS™ program
- Information about THALOMID and the THALOMID REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**

For more information about THALOMID and the THALOMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo)) ((THALOMID REMS™ logo)) ((THALOMID logo))

Initial prescription (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain 2 negative pregnancy tests sensitive to at least 50 mIU/mL, even if continuous abstinence is the chosen method of birth control. One test must be obtained 10 to 14 days and one test within 24 hours prior to writing an initial prescription for THALOMID® (thalidomide).
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open THALOMID capsules and to maintain storage of capsules in blister packs until ingestion.
3. Obtain, review, and complete the THALOMID® (thalidomide) Patient-Physician Agreement Form online at **www.CelgeneRiskManagement.com**, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**.
 - **Males (adults and children)**
 - **Females of reproductive potential include all females who are menstruating**, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category
 - **Females not of reproductive potential include females who have been in natural menopause for at least 24 consecutive months**, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating
4. Send the completed and signed THALOMID® (thalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**.
5. Instruct female patients to complete a brief initial mandatory confidential survey at **www.CelgeneRiskManagement.com**, or by calling **1-888-423-5436**, prior to prescriber obtaining an authorization number.
 - Males do not need to complete the initial survey
6. Complete a prescriber brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written.
 - You will need to enter the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
7. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
8. Send the prescription to a certified pharmacy.

Subsequent prescriptions (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain scheduled pregnancy tests weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks.
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open THALOMID capsules and to maintain storage of capsules in blister packs until ingestion.
3. Instruct patient to complete a brief mandatory confidential survey **as scheduled**, prior to prescriber obtaining an authorization number and filling the prescription.
 - Monthly:
 - **Males (adults and children)**
 - **Females of reproductive potential (adults and children)**
 - **Female children not of reproductive potential**
 - Every 6 months:
 - **Adult females not of reproductive potential**
4. Complete a prescriber brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for every patient before each prescription is written.
 - You will need to enter the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
5. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
6. Send the prescription to a certified pharmacy.

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[Front]

THALOMID REMS™ Prescriber Enrollment Form

All prescribers must be certified to prescribe THALOMID® (thalidomide). To become certified the prescriber must:

1. Complete the Prescriber Enrollment Form, which is required for THALOMID REMS™ (formerly known as the *S.T.E.P.S.*® program) certification.
2. Agree to steps on the following page that must be followed with every patient.

To submit this form electronically, please go to www.CelgeneRiskManagement.com.

To submit this form via fax, please complete the following page and fax it to 1-888-432-9325.

THALOMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID provided adequate precautions are taken to avoid pregnancy.

Please review the steps on the following page that must be followed with every patient.

THALOMID is only available under a restricted distribution program, THALOMID REMS™.

((THALOMID logo))

[Back]

THALOMID REMS™ Prescriber Enrollment Form

When prescribing THALOMID® (thalidomide), I agree to:

- Provide patient counseling on the benefits and risks of THALOMID therapy, including Boxed Warnings
- Submit a completed THALOMID® (thalidomide) Patient-Physician Agreement Form for each new patient
- Provide contraception and emergency contraception counseling with each new prescription prior to and during THALOMID treatment
- Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions
- Report any pregnancies in female patients or female partners of male patients prescribed THALOMID immediately to Celgene Drug Safety (or Celgene Customer Care Center)
- Complete a mandatory and confidential prescriber survey online or by telephone for all patients and obtain a new authorization number for each prescription written and include this authorization number on the prescription
- Facilitate female patient compliance with an initial mandatory confidential patient survey online or by telephone
- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- Contact a THALOMID REMS™ certified pharmacy to fill the prescription
- Return to Celgene all THALOMID capsules that are returned by patients. Shipping fees will be paid by Celgene Corporation. To arrange returns, call the Celgene Customer Care Center
- Remind patients to return all THALOMID capsules to Celgene Corporation or their THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to them
- Re-enroll patients in the THALOMID REMS™ program if THALOMID is required and previous therapy with THALOMID has been discontinued for 12 consecutive months

Please fill out the spaces below completely.

Prescriber Name _____

Degree: MD/DO/PA/NP/Fellow/Medical Resident Specialty _____

Prescriber Identification Number (eg, DEA Number, Social Security Number, NPI Number, etc.) _____

Please indicate which office(s) will receive THALOMID REMS™ materials and updates:

☐ Primary Office Name _____
Attention _____
Address _____
City _____ State _____ ZIP Code _____
Phone _____ Ext. _____ Fax _____
Email Address _____

☐ Secondary Office Name _____
Attention _____
Address _____
City _____ State _____ ZIP Code _____
Phone _____ Ext. _____ Fax _____
Email Address _____

I understand that if I fail to comply with all requirements of the THALOMID REMS™ program, my prescriptions for THALOMID® (thalidomide) will not be honored at certified pharmacies.

Prescriber Signature _____ Date _____

Return this form to the Celgene Customer Care Center via fax or mail.

Mail to: Celgene Customer Care Center, 86 Morris Avenue, Summit, NJ 07901

Phone: **1-888-423-5436**

Fax: **1-888-432-9325**

www.CelgeneRiskManagement.com

((Celgene logo))

((THALOMID REMS™ logo))

((THALOMID logo))

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REMS-THA13274

THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed THALOMID for you. THALOMID is available only through a restricted distribution program called THALOMID Risk Evaluation and Mitigation Strategy (REMS)[™] (formerly known as the *S.T.E.P.S.*[®] program). Before taking THALOMID, you must read and agree to all of the instructions in the THALOMID REMS[™] program.

If you are pregnant or become pregnant while taking THALOMID, it is important for you to know that your unborn baby can have severe birth defects or even die.

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the THALOMID Medication Guide.

INSTRUCTIONS

Before starting your treatment with THALOMID, you will need to:

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the THALOMID REMS[™] materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

Authorized Representatives:

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the THALOMID[®] (thalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the THALOMID[®] (thalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the THALOMID REMS[™] program and is authorized to consent to treatment with THALOMID on behalf of the patient.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

BAR CODE HERE

THALOMID (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement.
Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- ☐ THALOMID can cause severe birth defects or death to my unborn baby if I am pregnant or become pregnant during treatment
- ☐ I am not pregnant now and will not get pregnant while being treated with THALOMID
- ☐ It is possible for me to get pregnant if:
 - I am having my period (am menstruating), or
 - My period has stopped because of my treatment
 - And I have sex with a male
- ☐ Not having sex is the only birth control method that is 100% effective
- ☐ I am not breastfeeding now and will not breastfeed while being treated with THALOMID
- ☐ My THALOMID prescription is **only** for me and is not to be shared with others
- ☐ I have read and understood the THALOMID Patient Guide to THALOMID REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that THALOMID may cause
- ☐ My healthcare provider has reviewed this information with me and answered any questions I have asked
- ☐ I may be contacted by Celgene to assist with the THALOMID REMS™ program
- ☐ I will NOT donate blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

BAR CODE HERE

THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

- ☐ I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have sex with a male unless otherwise recommended by my doctor. My doctor may recommend that I use **at the same time** 2 different birth control methods **every time** I have sex with a male if I cannot use a hormonal or intrauterine device (IUD) method

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	Male latex or synthetic condom
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	+ Diaphragm
Tubal ligation (having your tubes tied)	Cervical cap
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	

- ☐ I will use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** I have sex with a male:
- Starting at least 4 weeks before taking THALOMID
 - While taking THALOMID
 - During breaks (dose interruptions)
 - For at least 4 weeks after stopping THALOMID

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

- ☐ I will have pregnancy tests—performed by my healthcare provider—according to the schedule listed below:
 - 10 to 14 days before receiving my first prescription for THALOMID, and again 24 hours before receiving my first prescription for THALOMID
 - Every week during the first 4 weeks of my treatment with THALOMID
 - Every 4 weeks during the rest of my treatment if I have a regular menstrual cycle or no cycle at all—**or**—every 2 weeks if I have an irregular menstrual cycle
- ☐ I will have these pregnancy tests even if I do not get my period because of my treatment
- ☐ I will need to take another pregnancy test performed by my healthcare provider if my medication is not dispensed within 7 days of taking my pregnancy test
- ☐ I will stop taking THALOMID and call my doctor right away if I:
 - Become pregnant while taking THALOMID, or
 - Miss my period or have unusual menstrual bleeding, or
 - Stop using birth control, or
 - Think—**for any reason**—that I am pregnant or may be pregnant
- ☐ If I become pregnant or think I may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my doctor is not available
- ☐ I will complete the mandatory confidential monthly survey while taking THALOMID
- ☐ I will keep my THALOMID prescription out of the reach of children
- ☐ I will return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused THALOMID capsules can also be returned to my THALOMID prescriber or to the pharmacy that dispensed the THALOMID to me

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Section 2. Authorization

I understand and confirm that:

- ☐ By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support[®], and other companies
 - Analyze data for internal business purposes on the use of THALOMID
 - Evaluate the effectiveness of the THALOMID REMS[™] program
 - Use in any other manner as required or permitted by law
 - Provide me with information about THALOMID or my condition
- ☐ This authorization will remain in effect for 12 months after I stop THALOMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the THALOMID REMS[™] program
- ☐ Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want to participate in the THALOMID REMS[™] program. I understand that by refusing to participate in the THALOMID REMS[™] program, I will not be able to receive THALOMID. However, I understand that I can speak with my doctor about other treatment options for my condition
- ☐ Upon signing this form, I authorize my healthcare provider to begin my treatment with THALOMID



THALOMID REMS[™]

THALOMID[®]
(thalidomide) Capsules

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the THALOMID REMS™ program, I will not be able to receive THALOMID. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of THALOMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with THALOMID (including appropriate birth control methods) and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the THALOMID REMS™ program.

Patient		Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Fax Number	Date of Birth
Sex		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature:
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the patient.

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed THALOMID for you. THALOMID is available only through a restricted distribution program called THALOMID Risk Evaluation and Mitigation Strategy (REMS)[™] (formerly known as the *S.T.E.P.S.*[®] program). Before taking THALOMID, you must read and agree to all of the instructions in the THALOMID REMS[™] program.

Any unborn baby of a female taking THALOMID can have severe birth defects or even die.

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the THALOMID Medication Guide.

INSTRUCTIONS *Before starting your treatment with THALOMID, you will need to:*

1. Complete sections 1 and 2 of this form and sign and date on page 5.
2. Read the THALOMID REMS[™] materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

Authorized Representatives:

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the THALOMID[®] (thalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the THALOMID[®] (thalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the THALOMID REMS[™] program and is authorized to consent to treatment with THALOMID on behalf of the patient.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- ☐ THALOMID can cause severe birth defects or death to unborn babies of females taking THALOMID
- ☐ I am not pregnant
- ☐ I am not able to get pregnant because:
 - I have had both of my ovaries and/or my uterus removed, or
 - I have been in menopause for at least 2 years
- ☐ My THALOMID prescription is **only** for me and is not to be shared with others
- ☐ I have read and understood the THALOMID Patient Guide to THALOMID REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that THALOMID may cause
- ☐ My healthcare provider has reviewed this information with me and answered any questions I have asked
- ☐ I may be contacted by Celgene to assist with the THALOMID REMS™ program

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

I will:

- ☐ I will complete the mandatory confidential survey every 6 months while taking THALOMID
- ☐ I will keep my THALOMID prescription out of the reach of children
- ☐ I will return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused THALOMID capsules can also be returned to my THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to me

I will not:

- ☐ I will **not** share my THALOMID capsules with anyone even if they have symptoms like mine
- ☐ I will **not** donate blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

Section 2. Authorization

I understand and confirm that:

- ☐ By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support[®], and other companies
 - Analyze data for internal business purposes on the use of THALOMID
 - Evaluate the effectiveness of the THALOMID REMS[™] program
 - Use in any other manner as required or permitted by law
 - Provide me with information about THALOMID or my condition
- ☐ This authorization will remain in effect for 12 months after I stop THALOMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the THALOMID REMS[™] program
- ☐ Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want to participate in the THALOMID REMS[™] program. I understand that by refusing to participate in the THALOMID REMS[™] program, I will not be able to receive THALOMID. However, I understand that I can speak with my doctor about other treatment options for my condition
- ☐ Upon signing this form, I authorize my healthcare provider to begin my treatment with THALOMID



THALOMID REMS[™]

THALOMID[®]
(thalidomide) Capsules

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Female Who Can Not Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the THALOMID REMS™ program, I will not be able to receive THALOMID. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of THALOMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with THALOMID and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the THALOMID REMS™ program.

Patient		Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Fax Number	Date of Birth
Sex		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature:
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the patient.

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed THALOMID for your child.* THALOMID is available only through a restricted distribution program called THALOMID Risk Evaluation and Mitigation Strategy (REMS)[™] (formerly known as the *S.T.E.P.S.*[®] program). Before taking THALOMID, patients must read and agree to all of the instructions in the THALOMID REMS[™] Program.

If your child is pregnant or becomes pregnant while taking THALOMID, it is important to know that the unborn baby can have severe birth defects or even die.

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the THALOMID Medication Guide.

INSTRUCTIONS

Before your child starts treatment with THALOMID, you will need to:

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the THALOMID REMS[™] materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- ☐ THALOMID can cause severe birth defects or death to the unborn baby if my child is pregnant or becomes pregnant during treatment
- ☐ My child is not pregnant now and will not get pregnant while being treated with THALOMID
- ☐ It is possible for my child to get pregnant if:
 - She has her period (is menstruating) or has shown any sign of puberty, or
 - Her period has stopped because of treatment
 - And she has sex with a male
- ☐ Not having sex is the only birth control method that is 100% effective
- ☐ My child is not breastfeeding now and will not breastfeed while being treated with THALOMID
- ☐ My child's THALOMID prescription is **only** for her and is not to be shared with others
- ☐ We have read and understood the THALOMID Patient Guide to THALOMID REMS[™] Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that THALOMID may cause
- ☐ My child's healthcare provider has reviewed this information with us and answered any questions we have asked
- ☐ We may be contacted by Celgene to assist with the THALOMID REMS[™] program
- ☐ My child will NOT donate blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

I will tell my child that:

- ☐ She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male unless otherwise recommended by her doctor. Her doctor may recommend that she use **at the same time** 2 different birth control methods **every time** she has sex with a male if she cannot use a hormonal or intrauterine device (IUD) method

Unless she chooses not to have sexual intercourse with a male at any time (abstinence), she must always use acceptable birth control

Highly effective birth control methods		Additional effective birth control methods	
Intrauterine device (IUD)	+	Male latex or synthetic condom	
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)		Diaphragm	
Tubal ligation (having your tubes tied)		Cervical cap	
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)			

- ☐ She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male:

- Starting at least 4 weeks before taking THALOMID
- While taking THALOMID
- During breaks (dose interruptions)
- For at least 4 weeks after stopping THALOMID

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

- ☐ She must have pregnancy tests—performed by her healthcare provider—according to the schedule listed below:
 - 10 to 14 days before receiving her first prescription for THALOMID, and again 24 hours before receiving her first prescription for THALOMID
 - Every week during the first 4 weeks of her treatment with THALOMID
 - Every 4 weeks during the rest of her treatment if she has a regular menstrual cycle or no cycle at all—**or**—every 2 weeks if she has an irregular menstrual cycle
- ☐ She must have these pregnancy tests even if she does not get her period because of her treatment
- ☐ She must take another pregnancy test performed by her healthcare provider if her medication is not dispensed within 7 days of taking her pregnancy test
- ☐ She must stop taking THALOMID and I will call her doctor right away if she:
 - Becomes pregnant while taking THALOMID, or
 - Misses her period or has unusual menstrual bleeding, or
 - Stops using birth control, or
 - Thinks—**for any reason**—that she is pregnant or may be pregnant
- ☐ If she becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my child's doctor is not available
- ☐ We will complete the mandatory confidential monthly survey while she is taking THALOMID
- ☐ We will keep her THALOMID prescription out of the reach of other children
- ☐ We will return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules my child did not take. Unused THALOMID capsules can also be returned to my child's THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to my child

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

Section 2. Authorization

I understand and confirm that:

- ☐ By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support[®], and other companies
 - Analyze data for internal business purposes on the use of THALOMID
 - Evaluate the effectiveness of the THALOMID REMS[™] program
 - Use in any other manner as required or permitted by law
 - Provide me and my child with information about THALOMID or my child's condition
- ☐ This authorization will remain in effect for 12 months after my child stops THALOMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the THALOMID REMS[™] program
- ☐ Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want my child to participate in the THALOMID REMS[™] program. I understand that by refusing to have my child participate in the THALOMID REMS[™] program, she will not be able to receive THALOMID. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition
- ☐ Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with THALOMID**



THALOMID REMS[™]

THALOMID[®]
(thalidomide) Capsules

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the THALOMID REMS™ program, she will not be able to receive THALOMID. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of THALOMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with THALOMID (including appropriate birth control methods) and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the THALOMID REMS™ program.

Patient		Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Fax Number	Date of Birth
Sex		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature:
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the parent/guardian.

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Male

Please read the following statements carefully.

Your doctor has prescribed THALOMID for you. THALOMID is available only through a restricted distribution program called THALOMID Risk Evaluation and Mitigation Strategy (REMS)[™] (formerly known as the *S.T.E.P.S.*[®] program). Before taking THALOMID, you must read and agree to all of the instructions in the THALOMID REMS[™] program.

If a female you have sex with is pregnant or becomes pregnant by you while you are taking THALOMID, it is important for you to know that your unborn baby can have severe birth defects or even die.

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the THALOMID Medication Guide.

INSTRUCTIONS

Before starting your treatment with THALOMID, you will need to:

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the THALOMID REMS[™] materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

Authorized Representatives:

If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the THALOMID[®] (thalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the THALOMID[®] (thalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the THALOMID REMS[™] program and is authorized to consent to treatment with THALOMID on behalf of the patient.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Male

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- ☐ THALOMID can cause severe birth defects or death to my unborn baby if I have sex with a female who is pregnant or who is able to get pregnant during my treatment
- ☐ My semen may contain THALOMID even after I stop treatment. I must use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID
- ☐ Not having sex is the only birth control method that is 100% effective
- ☐ My THALOMID prescription is **only** for me and is not to be shared with others
- ☐ I have read and understood the THALOMID Patient Guide to THALOMID REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that THALOMID may cause
- ☐ My healthcare provider has reviewed this information with me and answered any questions I have asked
- ☐ I may be contacted by Celgene to assist with the THALOMID REMS™ program

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Male

- ☐ I will use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant, even if I have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- ☐ I will use a latex or synthetic condom **every time** I have sex with a female who is pregnant or who is able to get pregnant:
 - While taking THALOMID
 - During breaks (dose interruptions)
 - For 4 weeks after stopping THALOMID
- ☐ I will call my doctor right away if I:
 - Have unprotected sex with a female who is pregnant or who is able to get pregnant
 - Think—**for any reason**—that my sexual partner is pregnant or may be pregnant
- ☐ If my partner becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my doctor is not available
- ☐ I will complete the mandatory confidential monthly survey while taking THALOMID
- ☐ I will keep my THALOMID prescription out of the reach of children
- ☐ I will return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused THALOMID capsules can also be returned to my THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to me

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Male

- ☐ I will **not** share my THALOMID capsules with anyone even if they have symptoms like mine
- ☐ I will **not** donate blood or sperm while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID

Section 2. Authorization

I understand and confirm that:

- ☐ By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support[®], and other companies
 - Analyze data for internal business purposes on the use of THALOMID
 - Evaluate the effectiveness of the THALOMID REMS[™] program
 - Use in any other manner as required or permitted by law
 - Provide me with information about THALOMID or my condition

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Male

- ☐ This authorization will remain in effect for 12 months after I stop THALOMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the THALOMID REMS[™] program
- ☐ Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want to participate in the THALOMID REMS[™] program. I understand that by refusing to participate in the THALOMID REMS[™] program, I will not be able to receive THALOMID. However, I understand that I can speak with my doctor about other treatment options for my condition
- ☐ Upon signing this form, I authorize my healthcare provider to begin my treatment with THALOMID



THALOMID REMS[™]

THALOMID[®]
(thalidomide) Capsules

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Adult Male

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the THALOMID REMS™ program, I will not be able to receive THALOMID. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of THALOMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if he has any questions regarding his treatment with THALOMID (including appropriate birth control methods) and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the THALOMID REMS™ program.

Patient	Prescriber
Name	Name
Identification Number	Identification Number
Address	Address
Telephone Number	Telephone Number
Date of Birth	Fax Number
Sex	
Diagnosis	
Patient or Authorized Representative's Signature:	Prescriber's Signature:
Signature Date:	Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the patient.

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed THALOMID for your child.* THALOMID is available only through a restricted distribution program called THALOMID Risk Evaluation and Mitigation Strategy (REMS)[™] (formerly known as the *S.T.E.P.S.*[®] program). Before taking THALOMID, patients must read and agree to all of the instructions in the THALOMID REMS[™] program.

Any unborn baby of a girl taking THALOMID can have severe birth defects or even die.

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the THALOMID Medication Guide.

INSTRUCTIONS

Before your child starts treatment with THALOMID, you will need to:

1. Complete sections 1 and 2 of this form and sign and date on page 5.
2. Read the THALOMID REMS[™] materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

BAR CODE HERE

THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- ☐ THALOMID can cause severe birth defects or death to unborn babies of females taking THALOMID
- ☐ My child is not pregnant
- ☐ My child is not able to get pregnant because she has not yet started her period (is not menstruating)
- ☐ My child's THALOMID prescription is **only** for her and is not to be shared with others
- ☐ We have read and understood the THALOMID Patient Guide to THALOMID REMS[™] Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that THALOMID may cause
- ☐ My child's healthcare provider has reviewed this information with us and answered any questions we have asked
- ☐ We may be contacted by Celgene to assist with the THALOMID REMS[™] program

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

I will tell my child that:

- ☐ We will complete the mandatory confidential monthly survey while my child is taking THALOMID
- ☐ We will keep my child's THALOMID prescription out of the reach of other children
- ☐ We will return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules my child did not take. Unused THALOMID capsules can also be returned to my child's THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to my child
- ☐ She must **not** share THALOMID capsules with anyone even if they have symptoms like hers
- ☐ She must **not** donate blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

Section 2. Authorization

I understand and confirm that:

- ☐ By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support[®], and other companies
 - Analyze data for internal business purposes on the use of THALOMID
 - Evaluate the effectiveness of the THALOMID REMS[™] program
 - Use in any other manner as required or permitted by law
 - Provide me and my child with information about THALOMID or my child's condition
- ☐ This authorization will remain in effect for 12 months after my child stops THALOMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the THALOMID REMS[™] program
- ☐ Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want my child to participate in the THALOMID REMS[™] program. I understand that by refusing to have my child participate in the THALOMID REMS[™] program, she will not be able to receive THALOMID. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition
- ☐ Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with THALOMID**



THALOMID REMS[™]

THALOMID[®]
(thalidomide) Capsules

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Female Child Who Can Not Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the THALOMID REMS™ program, she will not be able to receive THALOMID. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of THALOMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with THALOMID and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the THALOMID REMS™ program.

Patient		Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Fax Number	Date of Birth
Sex		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature:
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the parent/guardian.

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Male Child

Please read the following statements carefully.

Your doctor has prescribed THALOMID for your child.* THALOMID is available only through a restricted distribution program called THALOMID Risk Evaluation and Mitigation Strategy (REMS)[™] (formerly known as the *S.T.E.P.S.*[®] program). Before taking THALOMID, patients must read and agree to all of the instructions in the THALOMID REMS[™] program.

If a female your child has sex with is pregnant or becomes pregnant by your child while he is taking THALOMID, it is important to know that the unborn baby can have severe birth defects or even die.

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

For more information, please see the THALOMID Medication Guide.

INSTRUCTIONS

Before your child starts treatment with THALOMID, you will need to:

1. Complete sections 1 and 2 of this form and sign and date on page 6.
2. Read the THALOMID REMS[™] materials contained in the **Patient Resource Pack**.
3. Keep a copy of this form for your records.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Male Child

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I understand and confirm that:

- ☐ THALOMID can cause severe birth defects or death to the unborn baby if my child has sex with a female who is pregnant or who is able to get pregnant during his treatment
- ☐ My child's semen may contain THALOMID even after he stops treatment. He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID
- ☐ Not having sex is the only birth control method that is 100% effective
- ☐ My child's THALOMID prescription is **only** for him and is not to be shared with others
- ☐ We have read and understood the THALOMID Patient Guide to THALOMID REMS™ Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that THALOMID may cause
- ☐ My child's healthcare provider has reviewed this information with us and answered any questions we have asked
- ☐ We may be contacted by Celgene to assist with the THALOMID REMS™ program

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Male Child

I will tell my child that:

- ☐ He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant, even if he has had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- ☐ He must use a latex or synthetic condom **every time** he has sex with a female who is pregnant or who is able to get pregnant:
 - While taking THALOMID
 - During breaks (dose interruptions)
 - For 4 weeks after stopping THALOMID
- ☐ I will call his doctor right away if he:
 - Has unprotected sex with a female who is pregnant or who is able to get pregnant
 - Thinks—**for any reason**—that his sexual partner is pregnant or may be pregnant
- ☐ If my child's partner becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at **1-888-423-5436** or the Emergency Contraception Hotline at **1-888-668-2528** for information about emergency contraception if my child's doctor is not available
- ☐ We will complete the mandatory confidential monthly survey while my child is taking THALOMID
- ☐ We will keep his THALOMID prescription out of the reach of other children
- ☐ We will return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**. Celgene will pay for the shipping costs. I understand that Celgene cannot give us a refund for the capsules my child did not take. Unused THALOMID capsules can also be returned to my child's THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to my child

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Male Child

- ☐ He must **not** share his THALOMID capsules with anyone even if they have symptoms like his
- ☐ He must **not** donate blood or sperm while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID

Section 2. Authorization

I understand and confirm that:

- ☐ By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support[®], and other companies
 - Analyze data for internal business purposes on the use of THALOMID
 - Evaluate the effectiveness of the THALOMID REMS[™] program
 - Use in any other manner as required or permitted by law
 - Provide me and my child with information about THALOMID or my child's condition

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Male Child

- ☐ This authorization will remain in effect for 12 months after my child stops THALOMID. However, it may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the THALOMID REMS[™] program
- ☐ Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want my child to participate in the THALOMID REMS[™] program. I understand that by refusing to have my child participate in the THALOMID REMS[™] program, he will not be able to receive THALOMID. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition.
- ☐ Upon signing this form, **I authorize my child's healthcare provider to begin my child's treatment with THALOMID**



THALOMID REMS[™]

THALOMID[®]
(thalidomide) Capsules

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THALOMID[®] (thalidomide) Patient-Physician Agreement Form

Male Child

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the THALOMID REMS[™] program, he will not be able to receive THALOMID. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of THALOMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient and his parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and his parent/guardian if they have any questions regarding the child's treatment with THALOMID (including appropriate birth control methods) and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the THALOMID REMS[™] program.

Patient	Prescriber
Name	Name
Identification Number	Identification Number
Address	Address
Telephone Number	Telephone Number
Date of Birth	Fax Number
Sex	
Diagnosis	
Patient or Authorized Representative's Signature:	Prescriber's Signature:
Signature Date:	Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.
Give a copy of the form to the parent/guardian.

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[Housing Unit Front Cover Flap]

((THALOMID REMS™ logo))

THALOMID Risk Evaluation and Mitigation Strategy (REMS)™ program education and prescribing safety kit

[Housing Unit Front Cover]

Risks of THALOMID® (thalidomide)

- If THALOMID is used during pregnancy, it can cause birth defects or embryo-fetal death. THALOMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking THALOMID
- THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

THALOMID in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

((THALOMID logo))

[Housing Unit Spine]

**THALOMID Risk Evaluation and Mitigation Strategy (REMS)[™] program education
and prescribing safety kit**

[Housing Unit Back Cover]

((THALOMID REMS™ logo))

Prescriber quick reference guide

1. The prescriber provides comprehensive counseling.
2. The prescriber verifies negative pregnancy test for all female patients of reproductive potential.
3. The prescriber completes THALOMID® (thalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene.
4. Female patients complete initial mandatory confidential survey by:
 - Visiting **www.CelgeneRiskManagement.com**, or
 - Calling Celgene Customer Care Center at **1-888-423-5436**Male patients do not need to complete the initial survey.
All patients must complete subsequent mandatory confidential surveys as outlined in the Prescriber Guide to THALOMID REMS™ Program (formerly known as the *S.T.E.P.S.*® program).
5. The prescriber completes mandatory confidential survey and receives authorization number by:
 - Visiting **www.CelgeneRiskManagement.com**, or
 - Calling Celgene Customer Care Center at **1-888-423-5436**
6. The prescriber writes THALOMID prescription and includes authorization number and patient risk category
7. The prescriber sends prescription to certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the THALOMID REMS™ procedures.

THALOMID is only available under a restricted distribution program, THALOMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo))

((THALOMID REMS™ logo))

((THALOMID logo))

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((THALOMID REMS™ logo))

Program for THALOMID® (thalidomide)

Education and Prescribing Safety

Dear Prescriber:

Enclosed are your THALOMID REMS™ program education materials

Celgene Corporation is pleased to provide you with the enclosed materials for use in the THALOMID REMS™ program (formerly known as the *S.T.E.P.S.*® program).

Important information about the THALOMID REMS™ program

- To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called “THALOMID REMS™”
- THALOMID is contraindicated in pregnant females and females of reproductive potential who are not using acceptable contraception or continually abstaining from heterosexual sexual contact. Females of reproductive potential may be treated with THALOMID provided adequate precautions are taken to avoid pregnancy
- Male Patients: Thalidomide is present in semen. Male patients taking THALOMID should not donate sperm. Males receiving THALOMID must always use a latex or synthetic condom during any sexual contact with females of reproductive potential even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with the THALOMID REMS™ program can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS™ program

As a prescriber certified with the THALOMID REMS™ program, please review and familiarize yourself with the contents of the enclosed THALOMID REMS™ Kit:

Prescriber Materials

- THALOMID REMS™ software and Installation Guide
- Prescriber Guide to THALOMID REMS™ Program
- THALOMID Full Prescribing Information

Patient Materials (Patient Resource Pack)

- Patient Guide to THALOMID REMS™ Program
- Emergency Contraception Brochure
- MEDICATION GUIDE

To order additional Patient Resource Packs, or if you have any questions about using the enclosed software, please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,

Jerome B. Zeldis, MD, PhD

Chief Medical Officer

Enclosures

Risks of THALOMID® (thalidomide)

- If THALOMID is used during pregnancy, it can cause birth defects or embryo-fetal death. THALOMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking THALOMID
- THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

THALOMID in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma. The effectiveness of THALOMID is based on response rates (see CLINICAL STUDIES section). There are no controlled trials demonstrating a clinical benefit, such as an improvement in survival.

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

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((THALOMID REMS™ logo))

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[Front Cover]

Pharmacy Guide to

((THALOMID REMS™ logo))

Risk Evaluation and Mitigation Strategy (REMS)™ Program

Important information about THALOMID® (thalidomide) and the THALOMID REMS™ program

- THALOMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called “THALOMID REMS™” (formerly known as the *S.T.E.P.S.*® program)
- Only prescribers and pharmacies certified with the THALOMID REMS™ program can prescribe and dispense the product to patients who are enrolled and meet all the conditions of the THALOMID REMS™ program
- Dispensing pharmacists must be educated on the THALOMID REMS™ program and on dispensing procedures for THALOMID
- Information about THALOMID and the THALOMID REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**

((THALOMID logo))

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Guidelines for ordering, counseling, and dispensing THALOMID® (thalidomide)

Dispensing pharmacies must be certified in the THALOMID REMS™ program with Celgene and must be educated in the following dispensing procedures.

Step 1. Review incoming THALOMID prescriptions

- A. Only accept prescriptions with an authorization number and patient risk category written on them.
 - Authorization numbers are valid for 7 days from the date of last pregnancy test for female patients of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted
 - Faxed prescriptions are permissible depending on state laws
- B. Make sure the prescription is signed and dated.
- C. Confirm the prescription is written for a 4-week (28-day) supply or less.
- D. For subsequent prescriptions, verify there are 7 days or less remaining of therapy on the existing prescription.

Step 2. Counsel patients

- A. Make sure a **certified THALOMID REMS™** counselor counsels the patient.
- B. Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist and ensure the form is signed and dated. Ensure the appropriate boxes are checked off. Retain a copy of the checklist and record of the associated prescription.
- C. If the patient mentions adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID, make sure to document these experiences using acceptable documentation as noted on the checklist.
 - **Acceptable documentation examples:**
 - 1. Celgene Adverse Drug Event form and fax confirmation
 - 2. Pharmacy log
- D. Report adverse drug experiences that are suspected to be associated with the use of THALOMID to Celgene Drug Safety within 24 hours. See the Adverse Drug Experience Reporting Procedure on page 7 for more information.

Guidelines for ordering, counseling, and dispensing THALOMID® (thalidomide) (continued)

Step 3. Obtain confirmation number from Celgene Customer Care

- A. Prior to each prescription, contact Celgene Customer Care at **1-888-423-5436**, available 24 hours a day, 7 days a week. Eligible pharmacies may also use the Celgene REMS Pharmacy Portal at www.CelgeneREMSPharmacyPortal.com. Call your Celgene Account Manager to see if your pharmacy is eligible.
- Enter the pharmacy NABP number or DEA number
 - Enter the authorization number written on the prescription
 - Enter the number of capsules and milligram strength being dispensed
- B. Write the confirmation number and the date of receipt on the prescription. The confirmation number is only valid for 24 hours.
- C. If you do not obtain a confirmation number, do not dispense THALOMID.

Step 4. Dispensing

- A. No Refills. A new prescription is required for each dispense. **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription.**
- B. Ensure the confirmation number has not expired, ie, dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **Do Not Dispense**. You must call Celgene Customer Care at **1-888-423-5436** to cancel the first confirmation number and obtain a new confirmation number. For female patients of reproductive potential, ship the same day or hand to the patient within 24 hours.
- C. Dispense each prescription with a Medication Guide and maintain a record on acceptable documentation.

Acceptable documentation examples:

1. Signed Education and Counseling Checklist (if counseling pharmacist and dispensing pharmacist are the same)
2. Pharmacy log

- D. Document the dispense date and maintain a record on acceptable documentation

Acceptable documentation examples:

1. Shipping receipt

2. Pharmacy dispensing log

- E. Dispense no more than a 4-week (28-day) supply. A new prescription is required for each dispense. No automatic refills or telephone prescriptions are permitted.
- F. A signature is required for all shipping and dispense if picked up by patient.

Step 5. Perform drug accountability

- A. Pharmacy shall keep an inventory log for THALOMID, by strength, reflecting its on-hand inventory at all times.
- B. Do not transfer THALOMID to another pharmacy without prior authorization from Celgene.
- C. Accept unused THALOMID (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal.

THALOMID Risk Evaluation Mitigation Strategy (REMS)[™] Education and Counseling Checklist for Pharmacies

Ensure your patients know the risks

Before you are able to fill a prescription for THALOMID[®] (thalidomide), a checklist for each patient must be completed based on the patient risk category (written on the front of the Patient Prescription Form). When completing the checklist, be sure all the appropriate boxes are checked off ([✓]) and the form is signed and dated. All boxes and spaces must be marked or filled in during counseling with the patient for every prescription. Retain a copy of the checklist and record of the associated prescription.

Be prepared to provide the following information for each checklist: ((IMAGE OF CHECKLIST))

Authorization Number	Confirmation Number	Confirmation Date
Pharmacy Name	Pharmacy Address (including City, State, ZIP Code)	
Counselor Name	Work Phone Number	Extension
Patient Name	Patient Date of Birth	

Rules for dispensing and shipping

Making sure before you release THALOMID

DO NOT DISPENSE OR SHIP THALOMID TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:

- Prescription has an authorization number and patient risk category written on it
- You have obtained a confirmation number and a confirmation date
- You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained
- The Medication Guide is included with the prescription
- You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing THALOMID prescription

For further information about THALOMID, please refer to the full Prescribing Information, enclosed.

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of THALOMID®(thalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID to Celgene using any of the following methods.

REPORTING TO CELGENE

- Email: **drugsafety@celgene.com**
- Telephone: **1-908-673-9667**
- Toll-free: **1-800-640-7854** (Global Drug Safety & Risk Management) or **1-888-423-5436** (Celgene Customer Care Center)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online at: **<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>**
- Telephone: **1-800-332-1088**
- Fax: **1-800-332-0178**
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

[Back Cover]

For more information about THALOMID® (thalidomide) and the THALOMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation

86 Morris Ave

Summit, NJ 07901

THALOMID is only available under a restricted distribution program, THALOMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo))

((THALOMID REMS™ logo))

((THALOMID logo))

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((THALOMID REMS™ logo))

Education and Counseling Checklist for Pharmacies

THALOMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the *S.T.E.P.S.*® program) education and prescribing safety

Authorization No.: Confirmation No.: Confirmation Date:

Pharmacy Name:

Pharmacy Address:

Counselor Name: Work Phone: Ext.:

Patient Name: Date of Birth:

Risk Category:

Checklist for female patients of reproductive potential

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

☐ Potential embryo-fetal toxicity

☐ Not taking THALOMID® (thalidomide) if pregnant or breastfeeding

☐ Using **at the same time** at least 1 highly effective method—tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—**every time they have sex with a male**, or abstaining from sex with a male

☐ Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking THALOMID, while taking THALOMID, during dose interruptions, and for at least 4 weeks after stopping THALOMID **every time they have sex with a male**, or abstaining from sex with a male

☐ Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks

- ☐ The need to stop taking THALOMID right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately
- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing THALOMID capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID
- ☐ Not breaking, chewing, or opening THALOMID capsules
- ☐ Instructions on THALOMID dose and administration

Milligram (mg) Strength _____ Number of Capsules Dispensed _____

FEMALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the THALOMID REMS™ education material and agreed to ensure compliance

Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)

- ☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing THALOMID capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID
- ☐ Not breaking, chewing, or opening THALOMID capsules

- ☐ Instructions on THALOMID dose and administration

Milligram (mg) Strength _____ Number of Capsules Dispensed _____

FEMALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the THALOMID REMS™ education material and agreed to ensure compliance
- ☐ Parent or legal guardian must inform the child's doctor when the child begins menses

Checklist for male patients

- ☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom **every time** when engaging in sexual intercourse with a female who can get pregnant)
- ☐ Female partners of males taking THALOMID® (thalidomide) must call their healthcare provider right away if they get pregnant
- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing THALOMID capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood or sperm while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID
- ☐ Not breaking, chewing, or opening THALOMID capsules
- ☐ Instructions on THALOMID dose and administration

Milligram (mg) Strength _____ Number of Capsules Dispensed _____

MALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the THALOMID REMS™ education material and agreed to ensure compliance

All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.

Counselor Signature: _____ **Date:** _____

For more information about THALOMID and the THALOMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation

86 Morris Ave

Summit, NJ 07901

THALOMID is only available under a restricted distribution program, THALOMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo))

((THALOMID REMS™ logo))

((THALOMID logo))

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REMS-THA13346

THALOMID REMS™ Pharmacy Certification Quiz

1. Authorization numbers for females of reproductive potential are valid for up to _____ days:
(Mandatory Question)
 - a. **7 days**
 - b. 10 days
 - c. 14 days
 - d. 28 days
2. It is not necessary to obtain a confirmation number to dispense. (Mandatory Question)
 - a. True
 - b. **False**
3. Celgene REMS programs are mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for each treatment.
(Mandatory Question)
 - a. **True**
 - b. False
4. It is not required to retain the prescription with the authorization and confirmation numbers for each filled prescription. It is not necessary to complete the Education and Counseling Checklist.
 - a. True
 - b. **False**
5. According to the package insert's boxed warnings and warnings and precautions, deep venous thrombosis and pulmonary embolism have been reported in patients receiving THALOMID.
(Mandatory Question)
 - a. **True**
 - b. False
6. THALOMID can cause serious birth defects. (Mandatory Question)
 - a. **True**
 - b. False
7. What pregnancy precautions are required for a female of reproductive potential with respect to heterosexual sexual contact?

- a. **Must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time she has sex with a male, beginning at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks after stopping therapy**
 - b. Abstain from having any heterosexual sexual contact only while taking therapy
 - c. After stopping therapy it is okay to get pregnant at any time
 - d. Use 2 forms of birth control 2 weeks before taking therapy
8. What precautions are required for a male with respect to sexual contact with his female partner of reproductive potential?
- a. **Use of a latex or synthetic condom every time he has sexual intercourse with a female of reproductive potential during therapy (including dose interruptions) and for 4 weeks after stopping therapy, even if he has undergone a successful vasectomy**
 - b. Abstain from having any sexual contact with a female of reproductive potential only while taking therapy
 - c. Use latex or synthetic condoms while taking therapy. No precautions are necessary once treatment has stopped
 - d. Males taking therapy who have had a vasectomy do not need to use latex or synthetic condoms
9. For all Celgene REMS programs, female patients of reproductive potential must have a negative pregnancy test: *(Mandatory Question)*
- a. Prior to initial prescription
 - b. Prior to subsequent prescription
 - c. **Prior to initial prescription and prior to subsequent prescription**
 - d. None of these
10. Adverse drug experiences that are suspected to be associated with the use of therapy, and any suspected pregnancy occurring during treatment, must be reported to Celgene. *(Mandatory Question)*
- a. **True**
 - b. False

11. The Medication Guide must be provided every time THALOMID is dispensed. (*Mandatory Question*)
- a. **True**
 - b. False
12. A certified Celgene REMS pharmacy cannot dispense more than a _____ supply of THALOMID.
- a. **28 day**
 - b. 3 month
 - c. 2 week
 - d. 1 year
13. Authorization numbers for patient risk categories other than females of reproductive potential are valid for up to _____ days. (*Mandatory Question*)
- a. **30 days**
 - b. 10 days
 - c. 7 days
 - d. 28 days
14. A male patient can donate sperm at any time during therapy.
- a. True
 - b. **False**

REMS-THA13250

((THALOMID REMS™ logo))

Patient Resource Pack

THALOMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the S.T.E.P.S.® program)

The Patient Resource Pack contains:

- Patient Guide to THALOMID REMS™ Program
- Emergency Contraception Brochure
- Medication Guide

THALOMID is only available under a restricted distribution program, THALOMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.

((Celgene logo))

((THALOMID logo))

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REMS-THA12129

[Front Cover]

Patient Guide to

((THALOMID REMS™ logo))

Risk Evaluation and Mitigation Strategy (REMS)™ Program

This guide provides you important information about:

- The risks of THALOMID® (thalidomide)
 - Birth defects (deformed babies) or death of an unborn baby
 - Blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)
- The THALOMID REMS™ program
 - What females who can get pregnant need to know
 - Birth control options
 - What females who can not get pregnant need to know
 - What males need to know

((THALOMID logo))

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Risks of THALOMID® (thalidomide)

THALOMID can cause harm to an unborn baby when given to a pregnant female. THALOMID causes a high frequency of severe and life-threatening birth defects (deformed babies) or death of an unborn baby, even after a single dose (1 capsule [regardless of strength]). THALOMID must not be used by pregnant females or by females who are able to get pregnant who are not using acceptable birth control or avoiding sex with a male. Females who are able to get pregnant must avoid pregnancy while taking THALOMID.

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

((Image of a baby with severe birth defects caused by THALOMID))

THALOMID can cause severe birth defects, including missing or severely deformed legs and arms. These babies often have hands attached directly to their shoulders and feet attached directly to their hips. Photo reprinted by permission.

What is the THALOMID REMS™ program?

To avoid serious risks to unborn babies, THALOMID is only available under a restricted distribution program called the “THALOMID Risk Evaluation and Mitigation Strategy (REMS)™” (formerly known as the *S.T.E.P.S.*® program). Only certified prescribers can prescribe THALOMID and only certified pharmacies can dispense THALOMID. In order to receive THALOMID, patients must be enrolled in the THALOMID REMS™ program and agree to follow the requirements.

For more information about THALOMID and the THALOMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center toll-free at **1-888-423-5436**.

((DO NOT GET PREGNANT logo))

What do all patients need to know about the THALOMID REMS™ program?

General guidelines

- This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. Just **one capsule** taken by a pregnant female can cause severe birth defects
- THALOMID® (thalidomide) does not induce abortion of the fetus and should never be used for contraception
- THALOMID must be kept out of the reach of children
- Do not open or unnecessarily handle THALOMID capsules. If a broken capsule (or the powder in the capsule) comes in contact with your skin, wash the area with soap and water
- Keep THALOMID in a cool, dry place
- Do **not** donate blood while you are taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID
- Unused THALOMID capsules should be returned for disposal to Celgene by calling **1-888-423-5436** or to your THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to you

WARNING

- **Blood clots** have been reported in patients taking THALOMID® (thalidomide), especially when used with other cancer drugs. Your healthcare provider may recommend treatment that could help prevent blood clots. Talk to your healthcare provider if you have shortness of breath, chest pains, or arm or leg swelling
- THALOMID can cause other health problems called “side effects.” For a complete listing of possible side effects, please refer to the Medication Guide
- **Be sure to report all side effects to your healthcare provider immediately.** Ask your healthcare provider about other side effects associated with THALOMID

((DO NOT GET PREGNANT logo))

What do females who can get pregnant need to know about the THALOMID REMS™ program?

A. Before taking THALOMID® (thalidomide)

- You must sign the THALOMID® (thalidomide) Patient-Physician Agreement Form that says you understand that THALOMID should not be used during pregnancy, and that you agree not to become pregnant while taking THALOMID
- If there is **any** chance that you can get pregnant, you must agree to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male starting at least 4 weeks **before** taking THALOMID
- Your healthcare provider must give you a pregnancy test 10 to 14 days before you receive your first prescription for THALOMID, and again within 24 hours before you receive your first prescription for THALOMID. If you are pregnant, you cannot take THALOMID
- You will have pregnancy tests before starting THALOMID and while taking THALOMID, even if you agree not to have sex with a male
- Before your healthcare provider can write your prescription for THALOMID, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies
- Before dispensing THALOMID® (thalidomide), your THALOMID REMS™ certified pharmacy will contact you to discuss treatment
- Your healthcare provider will talk with you about your birth control options

1. Choose at least 1 highly effective method and at least 1 additional effective method of birth control.

Talk to your healthcare provider about the following acceptable birth control methods. See below.

Reliable Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	Male latex or synthetic condom
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Diaphragm
	+ Cervical cap
Tubal ligation (having your tubes tied)	

Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	
--	--

2. Use the 2 methods of birth control at the same time

- **Remember:** You must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male. However, your healthcare provider may recommend that you use 2 different methods instead for medical reasons
- Talk to your healthcare provider to make sure that other medicines or dietary supplements you are taking do not interfere with your hormonal birth control methods
- **Remember, not having sex is the only method of birth control that is 100% effective**

3. Unacceptable methods of birth control

- Progesterone-only “mini-pills”
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield *

4. Take pregnancy tests

- You must have a pregnancy test performed by your healthcare provider 10 to 14 days before receiving your first prescription for THALOMID® (thalidomide) and again within 24 hours before receiving your first prescription for THALOMID. Both pregnancy tests must have a negative result

B. While taking THALOMID

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male

- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must talk to your healthcare provider before changing any birth control methods you have already agreed to use

*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

- You will have a pregnancy test performed by your healthcare provider:
 - Every week during the first 4 weeks of treatment, then
 - Every 4 weeks if your menstrual cycles are regular, or
 - Every 2 weeks if your cycles are irregular
 - If you miss your period or have unusual menstrual bleeding, or
 - If your medication is not dispensed within 7 days of taking the pregnancy test
- If you had sex with a male without using birth control, stop taking THALOMID® (thalidomide) immediately and call your healthcare provider right away
- If you get pregnant, or think you may be pregnant, you must **immediately** stop taking THALOMID. Contact your healthcare provider immediately to discuss your pregnancy. If you do not have an obstetrician, your healthcare provider will refer you to one for care and counseling. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must not breastfeed a baby while you are taking THALOMID
- In order to continue receiving THALOMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your THALOMID REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

C. After you have stopped taking THALOMID® (thalidomide)

- You must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male:
 - For at least 4 weeks after stopping THALOMID, or
 - Do not have any sex with a male for 4 weeks after stopping THALOMID

See also “General guidelines” on page 4 for requirements for all patients.

What do females who can not get pregnant need to know about the THALOMID REMS™ program?

A. Before taking THALOMID® (thalidomide)

- You must sign the THALOMID® (thalidomide) Patient-Physician Agreement Form that says you are currently not pregnant and are not able to get pregnant. This means that:
 - You have been in natural menopause for at least 2 years, or
 - You have had both ovaries and/or uterus removed
- For females who have not started their period (menstruation) and are under the age of 18, a parent or legal guardian must sign the THALOMID® (thalidomide) Patient-Physician Agreement Form that says the patient is not pregnant, is not able to get pregnant, and/or will not be having sex with a male for at least 4 weeks before starting THALOMID
- Before your healthcare provider can write your prescription for THALOMID, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies
- Before dispensing THALOMID, your THALOMID REMS™ certified pharmacy will contact you to discuss treatment

B. While taking THALOMID® (thalidomide)

- In order to continue receiving THALOMID, you must take part in a mandatory confidential survey every six months. You must also continue to discuss your treatment with your THALOMID REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

See also “General guidelines” on page 4 for requirements for all patients.

What do males need to know about the THALOMID REMS™ program?

You must use a latex or synthetic condom, **every time** you have sex with a female who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

A. Before taking THALOMID® (thalidomide)

- You must sign the THALOMID® (thalidomide) Patient-Physician Agreement Form. You must agree that while taking THALOMID you will use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant
- Before dispensing THALOMID, your THALOMID REMS™ certified pharmacy will contact you to discuss treatment

B. While taking THALOMID

- You must use a latex or synthetic condom **every time** (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must tell your healthcare provider right away if you have sex with a female without using a latex or synthetic condom, or if you think for any reason that your partner is or may be pregnant. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must **not** donate sperm while taking THALOMID® (thalidomide) (including during breaks [dose interruptions])
- In order to continue receiving THALOMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your THALOMID REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

C. After you have stopped taking THALOMID

- For 4 weeks after receiving your last dose of THALOMID, you must use a latex or synthetic condom, **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- You must **not** donate sperm for 4 weeks after stopping THALOMID

See also “General guidelines” on page 4 for requirements for all patients.

Mandatory confidential patient surveys

As a patient who is enrolled in the THALOMID REMS™ program for THALOMID® (thalidomide), you will need to complete a brief mandatory confidential survey as outlined below.

Adult females who can get pregnant

- Initial survey before first prescription
- Monthly

Adult females who can not get pregnant

- Initial survey before first prescription
- Every six months

Female children

- Initial survey before first prescription
- Monthly

Males

- No initial survey
- Monthly

Mandatory confidential survey process

- When your healthcare provider tells you to take the survey, go to the patient Mandatory Confidential Survey section of **www.CelgeneRiskManagement.com** or call the Celgene Customer Care Center at **1-888-423-5436**
- Be prepared with your patient identification number
- After completing your survey, your healthcare provider will also complete a survey. Your healthcare provider will then receive authorization to write your prescription
- The prescription will be sent to a THALOMID REMS™ certified pharmacy. The THALOMID REMS™ certified pharmacy will contact you to discuss your THALOMID therapy. You will not receive your medication until you speak with the THALOMID REMS™ certified pharmacy

For more information, contact the Celgene Customer Care Center at **1-888-423-5436**.

((TVAC icon))

A letter from the Thalidomide Victims Association of Canada (TVAC)

The following letter from the Thalidomide Victims Association of Canada (TVAC) was written in 1998 upon U.S. approval of THALOMID® (thalidomide), and is included in this brochure to be transparent about public concerns for thalidomide victims regarding the marketing of THALOMID.

Dear Doctor/Patient:

Have you ever met someone who was born disabled after exposure to thalidomide?

We have. In fact, we are thalidomiders—the name we have adopted to describe the surviving children of mothers who were prescribed thalidomide during their pregnancy as a sedative or for nausea and other symptoms of “morning sickness.”

You’ve undoubtedly seen the **dramatic photographs of babies with severe birth defects** caused when thalidomide is taken EVEN ONCE by a pregnant woman. You know the risks!

The **Thalidomide Victims Association of Canada** (TVAC) was formed to meet the needs of the approximately 125 thalidomiders alive in Canada today, and to aid the surviving 10 thalidomiders living in the United States. Of the 10,000 to 12,000 children born with thalidomide deformities around the world in the early sixties, 5,000 survive today. No one will ever know how many children were miscarried or were stillborn because of thalidomide.

TVAC exists as a survivors group to determine and find solutions to the ongoing problems we face. TVAC has also undertaken a mandate of monitoring the responsible use of thalidomide and ensuring the tragedy of the past *never happens again*.

Because of our own personal traumas, and those of our families, we have always stated that we can never accept a world with thalidomide in it.

However, as we know first-hand how people may suffer, we also concede that no one should suffer needlessly. If thalidomide can extend a life, or offer a better quality of life to people with debilitating or chronic illnesses, then we are forced to accept the fact that thalidomide use may be their choice.

As well, we are forced to prefer the regulated use of thalidomide over the alternative:

One thalidomide baby born out of ignorance is far worse than one born out of a legitimate attempt to regulate and control the distribution process of this drug.

Since you may soon be involved in prescribing or taking thalidomide, we need for you to be **fully aware of the power you have ...**

- the responsibility to see that you **fully understand the risks thalidomide poses ...**
- the **commitment** to do whatever it takes to make sure that NOT EVEN ONE woman loses a child due to thalidomide

We were as surprised as anyone when the people at Celgene Corporation, makers of THALOMID® (thalidomide), sought the opinions and input of those of us at TVAC concerning the use of thalidomide in the United States. We felt it was a respectful step in the right direction that our feelings, opinions, and knowledge were being considered.

We are also consoled to know that Celgene Corporation has instituted a comprehensive program to help physicians and pharmacists inform patients about side effects and risks and ensure that they are aware of precautions they must take before, during, and after therapy.

The **THALOMID Risk Evaluation and Mitigation Strategy (REMS)™** is a multifaceted program developed to help ensure that fetal exposure to THALOMID does not occur. All of the materials you need to comply with this system are enclosed.

Meanwhile, we make you one promise:

The Thalidomide Victims Association of Canada will continue to watch the progression of events where thalidomide use is concerned.

We have to!

For further information regarding the history of thalidomide or the status of survivors today, please feel free to contact us.

Sincerely,

((signatures))

Randolph Warren

Giselle Cole

Chief Executive Officer Past President

Thalidomide Victims

Thalidomide Victims

Association of Canada

Association of Canada

Head Office

Thalidomide Victims Association of Canada

Centre Commercial Joseph Renaud
6830 Boul. Joseph Renaud, Suite 211
Montreal, Quebec, Canada
H1K 3V4

Phone: **1-514-355-0811**

Fax: **1-514-355-0860**

((DO NOT GET PREGNANT logo))

Warning to patients taking THALOMID[®] (thalidomide)

Attention females:

Do **not** take THALOMID if you are pregnant, if you are breastfeeding, or if you are able to get pregnant and are not using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.

Attention males:

You must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm).

You must **not** donate sperm while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID.

Attention all patients:

You must **not** donate blood while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID.

This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. Just **one capsule** taken by a pregnant female can cause severe birth defects.

THALOMID must be kept out of the reach of children. Return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**, or to your THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to you.

[Back Cover]

For more information about THALOMID[®] (thalidomide) and the THALOMID REMS[™] program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation

86 Morris Ave

Summit, NJ 07901

THALOMID is only available under a restricted distribution program, THALOMID REMS[™].

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.

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((THALOMID REMS[™] logo))

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REMS-THA13247

Celgene logo

REMS Patient Survey Reminder

Patient Name _____ Date Survey Available _____

Doctor Office Contact and Phone # _____

Product _____ Pharmacy Name _____

Telephone Survey

OR

Website Survey



From a touchtone

phone dial

1-888-423-5436

Para español, oprime el
numero dos

to identify that you are a
patient

to take a survey

Enter your 9-digit patient
identification number
(the number you provided
during the enrollment—
for example your Social
Security Number).

Access the internet and type in the website address

www.CelgeneRiskManagement.com

You are not required to have a User Name or
Password to complete a survey. To take your
survey, left click your mouse on the button




You will be asked for the following information.
Please enter the information exactly as it was
provided during your enrollment process

A screenshot of a web form titled "Please enter your details in the form below to continue with the patient survey." It contains three input fields: "Patient Last Name:", "Patient First Name:", and "Patient Identification Number:". Below the third field, it says "Social Security Number e.g. 123456789". At the bottom, it says "Please be sure to complete the survey in its entirety and upon completion send to Celgene."

After entering the information above, click

CelgeneRiskManagement.com

Login Page



Welcome to the Celgene REMS Program

To avoid embryo-fetal exposure, Risk Evaluation and Mitigation Strategy (REMS) programs are mandatory for the Celgene products THALOMID® (thalidomide), REVLIMID® (lenalidomide) and POMALYST® (pomalidomide). The THALOMID REMS™ program (formerly known as the S.T.E.P.S.® program), REVLIMID REMS™ program (formerly known as the RevAssist® program), and POMALYST REMS™ program require prescribers and pharmacists to be certified and patients to enroll and comply with all of the requirements for each program.

If you would like to obtain more information about any of the Celgene REMS programs, please click on the program name below:

RevlimidREMS™
Visit www.REVLIMIDREMS.com,
to learn more about the
REVLIMID REMS™ program.

PomalystREMS™
Visit www.POMALYSTREMS.com,
to learn more about the
POMALYST REMS™ program.

THALOMIDREMS™
Visit www.THALOMIDREMS.com,
to learn more about the
THALOMID REMS™ program.

For prescribers, please enter your User Name and Password to manage your patients through a Celgene REMS program. If you do not have an online account, select Create User Account to establish an account. Patients currently enrolled in a Celgene REMS program are not required to create an online account to complete a survey. Please select Patient Surveys and enter the information requested to begin a survey.

To login to your account:

User Name

Password


[Forgot Password? >](#)

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Home Page (after prescriber logon)


first last

[Home](#) [Help](#) [Logout](#)

Home


Click on a button below to access the corresponding REMS menu of operations for that product: enroll a patient, access an existing or save a new Patient-Physician Agreement Form, complete a prescriber survey or write a prescription.

For **REVLIMID REMS™**
(formerly known as the RevAssist® program)




Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

For **POMALYST REMS™**



Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

For **THALOMID REMS™**
(formerly known as the S.T.E.P.S.® program)



Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

The Prescriber Dashboard is an optional resource that displays the status of patients under your care for a specific Celgene REMS program. A patient search function is also included to access detailed patient history information.

Select the "Manage My Account" button to view your Celgene REMS online account information.

[Prescriber Dashboard](#) [Manage My Account](#)

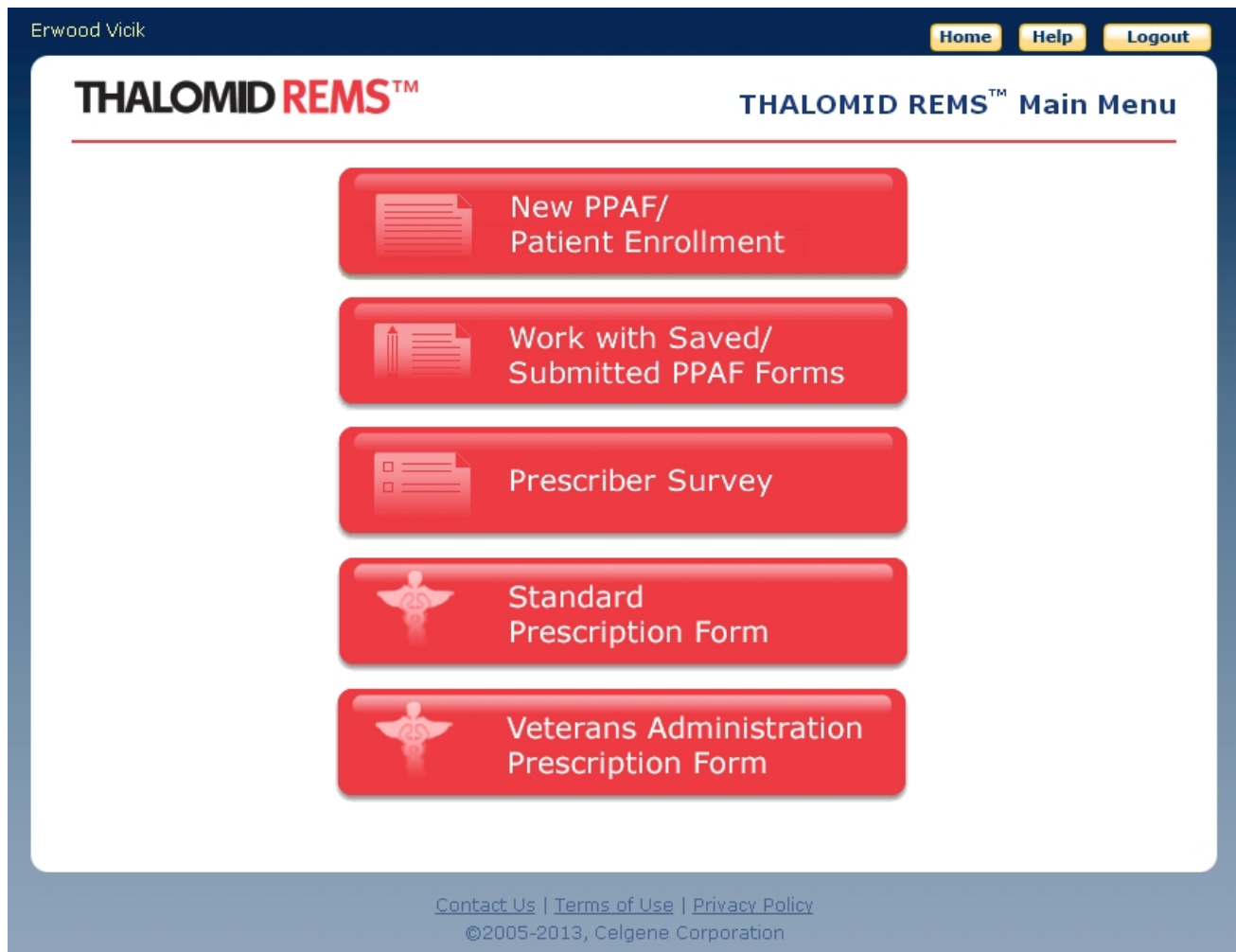
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Reference ID: 3627000

THALOMID REMS module



THALOMID REMS™



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[Pharmacist Resources](#)

For additional information about the THALOMID REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

Welcome to the THALOMID REMS™ program

THALOMID® (thalidomide) in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

Important information about THALOMID and the THALOMID Risk Evaluation and Mitigation Strategy (REMS)™ program

- THALOMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called "THALOMID REMS™" (formerly known as the S.T.E.P.S.® program)
- Only prescribers and pharmacies certified by the THALOMID REMS™ program can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS™ program

The goals of the THALOMID risk evaluation and mitigation strategy are as follows:

1. To prevent the risk of embryo-fetal exposure to THALOMID
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for THALOMID

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About the THALOMID REMS™ program

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To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called "THALOMID Risk Evaluation and Mitigation Strategy (REMS)™" (formerly known as the S.T.E.P.S.® program). Only certified prescribers can prescribe THALOMID and only certified pharmacies can dispense THALOMID in the THALOMID REMS™ program.

In order to receive THALOMID, all patients must be enrolled in the THALOMID REMS™ program and agree to comply with the requirements of the THALOMID REMS™ program.

Key points of the THALOMID REMS™ program

Prescriber

- The prescriber enrolls and becomes certified with Celgene for the THALOMID REMS™ program
- The prescriber counsels patient on benefits and risks of THALOMID
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a THALOMID® (thalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends THALOMID prescription to certified pharmacy

Pharmacy

- The pharmacy certifies with Celgene for the THALOMID REMS™ program
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy counsels the patient, and completes an Education and Counseling Checklist
- The certified pharmacy dispenses THALOMID to patient along with a Medication Guide

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For additional information about the THALOMID REMS™ program, please contact the Celgene Customer Care Center at 1-888-432-9325.

Prescriber Resources

THALOMID® (thalidomide) in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

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Enrolling in THALOMID REMS™

In order to prescribe THALOMID, you must enroll in the THALOMID REMS™ program (formerly known as the S.T.E.P.S.® program) and agree to follow the requirements of the program. You can enroll by visiting CelgeneRiskManagement.com, a website that allows prescribers to handle the REMS process for all of the Celgene REMS programs. You can also download the Prescriber Enrollment Form below and fax it to Celgene Customer Care at 1-888-432-9325.

Prescriber Enrollment Form

Prescribing THALOMID for your patients

In order to receive THALOMID, your patients must also be enrolled in the THALOMID REMS™ program. You can enroll your patients and fill out a prescription form using CelgeneRiskManagement.com. You and your patients can also complete your mandatory confidential surveys there.

Additionally, you can also enroll your patients and write prescriptions by downloading the Desktop Software and installing it on your computer.

Enroll Your Patients at
CelgeneRiskManagement.com

Desktop Software
Installation

Installation
User Guide

Patient Prescription Form

Learning more about THALOMID REMS™

For a complete overview of the THALOMID REMS™ program, and a guide to the THALOMID REMS™ process, please see the educational materials below.

Prescriber Guide
to THALOMID REMS™ Program



THALOMID REMS™
At-A-Glance



Full Prescribing Information



Please report adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID to Celgene using any of the following methods.

REPORTING TO CELGENE

Email: drugsafety@celgene.com

Telephone: 1-908-673-9667

Toll-free: 1-800-640-7854 (Global Drug Safety & Risk Management) or
1-888-423-5436 (Celgene Customer Care Center)

Fax: 1-908-673-9115

Mail to: Global Drug Safety & Risk Management
Celgene Corporation
300 Connell Dr.
Suite 6000
Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID may also be reported to the FDA MedWatch Reporting System using any of the following methods.

Online: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>

Telephone: 1-800-332-1088

Fax: 1-800-332-0178

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

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For additional information about the THALOMID REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

Patient Resources

THALOMID® (thalidomide) in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

What you need to know about the THALOMID REMS™ program

Your doctor will enroll you in the THALOMID REMS™ program (formerly known as the S.T.E.P.S.® program) so that you can receive your medication. Use the materials below to learn more about the THALOMID REMS™ program, and what you need to do.

[Patient Guide to THALOMID REMS™ Program](#)

[Patient Survey Reminder Card](#)

[Patient Medication Guide](#)

[Visit Planned Parenthood site for Emergency Contraception Brochure](#)

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THALOMID REMS™



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Pharmacist Resources

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THALOMID REMS™ information for certified pharmacies

THALOMID is only dispensed from THALOMID REMS™ program (formerly known as the S.T.E.P.S.® program) certified pharmacies. To learn more about how to become a certified pharmacy, please contact the Celgene Customer Care Center at 1-888-423-5436.

As a THALOMID REMS™ certified pharmacy, you must follow the requirements of the THALOMID REMS™ program. You may download a guide to the program, a checklist for counseling patients and the full prescribing information below.

Pharmacy Guide to THALOMID REMS™ Program

Education and Counseling Checklist for Pharmacies

Full Prescribing Information

The Celgene REMS Pharmacy Portal

In addition to calling the Celgene Customer Care Center to obtain a confirmation number for a prescription, eligible pharmacies can obtain confirmation numbers using the Celgene REMS Pharmacy Portal at CelgeneREMSPharmacyPortal.com. Contact your Celgene Account Manager to see if your pharmacy is eligible.

Celgene REMS Pharmacy Portal

Please report adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID to Celgene using any of the following methods:

REPORTING TO CELGENE

Email: drugsafety@celgene.com

Telephone: 1-908-673-9667

Toll-free: 1-800-640-7854 (Global Drug Safety & Risk Management) or
1-888-423-5436 (Celgene Customer Care Center)

Fax: 1-908-673-9115

Mail to: Global Drug Safety & Risk Management
Celgene Corporation
300 Connell Dr.
Suite 6000
Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

Online: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>

Telephone: 1-800-332-1088

Fax: 1-800-332-0178

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

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For additional information about the THALOMID REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

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LOMID Risk Evaluation

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program can prescribe and dispense
of the THALOMID REMS™ program

THALOMID to patients who are enrolled and meet all the conditions of

1. To prevent the risk of embryo-fetal exposure to THALOMID
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for THALOMID

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Prescriber Guide to **THALOMID REMS™** Risk Evaluation and Mitigation Strategy (REMS)™ Program

A known teratogen, THALOMID® (thalidomide) is approved for marketing only under a restricted distribution program approved by the Food and Drug Administration. This program is called the THALOMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the *S.T.E.P.S.*® program).

This guide contains important information for prescribers about:

- The risks of THALOMID, including a boxed warning for
 - Embryo-fetal toxicity
 - Venous thromboembolism (deep venous thrombosis [DVT] and pulmonary embolism [PE])
- The THALOMID REMS™ program
 - Prescriber Certification
 - Patient Enrollment
 - Contraceptive Requirements and Counseling for Patients
 - Initial and Subsequent Prescription Requirements

THALOMID REMS™ Resources for Prescribers Include:

- Prescriber Guide to THALOMID REMS™ Program
- CD-ROM, including Patient-Physician Agreement Form and Patient Prescription Form Software and Installation Instructions
- Full Prescribing Information for THALOMID

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About THALOMID® (thalidomide)

THALOMID in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

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THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

Risks of THALOMID

THALOMID has a Boxed Warning for embryo-fetal toxicity and venous thromboembolism (deep venous thrombosis [DVT] and pulmonary embolism [PE]).

A known teratogen, THALOMID is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID if they take adequate precautions to avoid pregnancy.

The use of THALOMID in MM results in an increased risk of venous thromboembolism, such as deep venous thrombosis and pulmonary embolism. This risk increases significantly when THALOMID is used in combination with standard chemotherapeutic agents including dexamethasone. Patients and physicians should be observant for the signs and symptoms of thromboembolism. Instruct patients to seek medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Consider thromboprophylaxis based on an assessment of individual patients’ underlying risk factors.

The THALOMID REMS™ program

To avoid embryo-fetal exposure, THALOMID® (thalidomide) is only available under a restricted distribution program called “THALOMID Risk Evaluation and Mitigation Strategy (REMS)™.” Only certified prescribers can prescribe THALOMID and only certified pharmacies can dispense THALOMID in the THALOMID REMS™ program.

In order to receive THALOMID, all patients must be enrolled in THALOMID REMS™ and agree to comply with the requirements of the THALOMID REMS™ program. Information about THALOMID and the THALOMID REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**.

Key points of the THALOMID REMS™ program

Prescriber

- The prescriber enrolls and becomes certified with Celgene for the THALOMID REMS™ program
- The prescriber counsels patient on benefits and risks of THALOMID
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a THALOMID® (thalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends THALOMID prescription to certified pharmacy

Pharmacy

- The pharmacy certifies with Celgene for THALOMID REMS™
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy dispenses THALOMID to patient along with a Medication Guide

THALOMID REMS™ patient enrollment

- Obtain, review, and complete the THALOMID® (thalidomide) Patient-Physician Agreement Form online at **www.CelgeneRiskManagement.com**, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**
- Prescribers who do not have access to a computer, or whose computer systems are not compatible with the software, will be provided with THALOMID REMS™ program materials. For additional assistance, please contact the Celgene Customer Care Center or your Celgene Hematology Oncology Consultant
- Patient, parent/legal guardian, and/or authorized representative must read the THALOMID® (thalidomide) Patient-Physician Agreement Form in the language of their choice

Help Ensure Timely Processing of Each Prescription

Fill Out Form as Directed

- Write only in the designated areas on the THALOMID® (thalidomide) Patient-Physician Agreement Form
- The box next to each statement must be marked (with an “X”) to indicate understanding
- The form must be completed and signed by both prescriber and patient

Instructions for Female Patients

- For female patients, the prescriber will need to provide information on whether the patient has been in surgical menopause, chemical menopause, or natural menopause for at least 24 months

Instructions for Minors

- If the patient is under 18 years of age, his or her legal guardian must read this material, mark the statement in each block of the form (with an “X”) and agree to ensure compliance by signing and dating the form

Instructions for Incompetent Adult Patients

- For an incompetent adult patient, an authorized representative must sign the THALOMID® (thalidomide) Patient-Physician Agreement Form
- An authorized representative is a caretaker authorized under applicable state law to consent to treatment on the incompetent patient’s behalf

THALOMID REMS™ patient enrollment (continued)

- The authorized representative must read the material, mark the statements, and agree to ensure compliance by signing and dating the form
- If the authorized representative does not have the power of attorney, **a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the THALOMID® (thalidomide) Patient-Physician Agreement Form.** This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the THALOMID® (thalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the THALOMID REMS™ program and is authorized to consent to treatment with THALOMID on behalf of the patient

Send in Completed Forms

- Send the completed THALOMID® (thalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**
- You will receive confirmation electronically or via fax to your office once the patient is enrolled
- Once the THALOMID® (thalidomide) Patient-Physician Agreement Form is received, both female patients and prescriber can take their surveys as required. Male patients do not take initial surveys
- In the event that you do not receive this confirmation within 15 minutes, call the Celgene Customer Care Center

Note: If therapy with THALOMID is discontinued for 12 consecutive months, the patient must enroll again in the THALOMID REMS™ program. Follow the above procedures to re-enroll the patient.

Initial prescription requirements

ALL PATIENTS

- Provide comprehensive counseling on the benefits and risks of therapy with THALOMID® (thalidomide)
- Patients must be counseled on the risks of birth defects, venous thromboembolism, other side effects, and important precautions associated with THALOMID
- Provide counseling not to share THALOMID capsules, and not to donate blood during treatment (including dose interruptions) and for 4 weeks after receiving their last dose of THALOMID, as well as counseling on appropriate contraceptive use, including emergency contraception
- Provide patients with education materials provided in the THALOMID REMS™ Patient Resource Pack
- Patients should be instructed to not extensively handle or open THALOMID capsules and to maintain storage of capsules in blister packs until ingestion
- Instruct patients to return unused THALOMID capsules for disposal to Celgene or to their THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to them

FEMALE PATIENTS

Determine if female patient is of reproductive potential

Two categories:

1. Females of Reproductive Potential

- All females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category

2. Females Not of Reproductive Potential

- Females who have been in natural menopause for at least 24 consecutive months, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating

Initial prescription requirements (continued)

1. Females of Reproductive Potential

Pregnancy test requirements

- Obtain a **negative** pregnancy test 10 to 14 days prior to writing an initial prescription for THALOMID® (thalidomide) and again within 24 hours prior to writing an initial prescription for THALOMID even if continuous abstinence is the chosen method of birth control
 - The pregnancy test must be sensitive to at least 50 mIU/mL
 - Pregnancy testing should occur weekly during the first 4 weeks of use
 - Pregnancy testing should be repeated every 4 weeks if patient has regular menses or is amenorrheic, or every 2 weeks if irregular menses
 - If a patient misses her period or if there is any abnormality in menstrual bleeding, THALOMID should be discontinued immediately. Obtain a pregnancy test and counsel the patient
- If pregnancy does occur during treatment, THALOMID must be immediately discontinued.** Any suspected embryo-fetal exposure to THALOMID must be reported immediately to the FDA via the MedWatch number at **1-800-332-1088** and also to the Celgene Customer Care Center at **1-888-423-5436**. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling
- The patient must not breastfeed a baby while being treated with THALOMID

Initial prescription requirements (continued)

Patient Counseling on Contraception Requirements

Contraception requirements

- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include using at the same time at least 1 highly effective method and at least 1 additional method of birth control every time they have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before THALOMID® (thalidomide) therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

Effective Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
<ul style="list-style-type: none">Intrauterine device (IUD)Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)Tubal ligation (having your tubes tied)Partner’s vasectomy (tying of the tubes to prevent the passing of sperm)	<ul style="list-style-type: none">Male latex or synthetic condomDiaphragmCervical cap

Remind all patients that not having any sexual intercourse is the only birth control method that is 100% effective.

Unacceptable forms of contraception:

- Progesterone-only “mini-pills”
 - IUD Progesterone T
 - Female condoms
 - Natural family planning (rhythm method) or breastfeeding
 - Fertility awareness
 - Withdrawal
 - Cervical shield*
- Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the effects of hormonal contraception. If hormonal or IUD contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after

*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

Initial prescription requirements (continued)

2. Females Not of Reproductive Potential

- The patient must confirm that she is currently not pregnant, nor of reproductive potential as she has been in natural menopause for at least 24 months, or had a hysterectomy and/or bilateral oophorectomy
- The parent or guardian must confirm that a prepubertal female child is not now pregnant, nor is of reproductive potential as **menstruation has not yet begun**, and/or the child will not be engaging in heterosexual sexual contact for at least 4 weeks before THALOMID® (thalidomide) therapy, during therapy, and for at least 4 weeks after stopping therapy

MALE PATIENTS

- Male patients must be instructed to use a latex or synthetic condom every time they have sexual intercourse with a female of reproductive potential, even if they have undergone a successful vasectomy. The risk to the developing baby from the semen of male patients taking THALOMID is unknown
- Male patients must be instructed not to donate sperm during treatment (including dose interruptions) and for 4 weeks after their last dose of THALOMID

Initial mandatory confidential survey

Females

- Instruct the female patient to complete a brief initial mandatory confidential survey at **www.CelgeneRiskManagement.com**, or by calling **1-888-423-5436**. See page 12 for subsequent prescription requirements

Males

- Males do not need to take the initial survey

Prescribers

- Prescriber will complete a brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or by calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written. Be prepared to enter some of the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supply (cannot exceed 28 days)
- An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted

ADDITIONAL INFORMATION FOR THE PRESCRIBER

- Healthcare provider must send the prescription to a THALOMID REMS™ certified pharmacy. To locate a certified pharmacy, please visit **www.Celgene.com/PharmacyNetwork**
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills

Subsequent prescription requirements

The prescriber must complete a brief mandatory confidential survey to obtain a new authorization number **every time** a prescription for THALOMID® (thalidomide) is written.

No automatic refills or telephone prescriptions are permitted. The patient risk category must be written on the prescription.

FEMALE PATIENTS

- Provide counseling as outlined in the “FEMALE PATIENTS” section on pages 7-10
- Follow pregnancy test requirements as outlined in “Pregnancy test requirements” section on page 8
- Female patients must complete a brief mandatory confidential survey according to the following schedule:
 - Before prescription is obtained
 - Monthly
 - Adult females of reproductive potential
 - All female children
 - Every 6 months
 - Adult females not of reproductive potential

MALE PATIENTS

- Provide patient counseling as outlined in the “MALE PATIENTS” section on page 10
- Male patients must complete a brief mandatory confidential survey once a month
 - Males do not complete an initial survey

After the last dose of THALOMID® (thalidomide)

After patients have stopped taking THALOMID, they must do the following:

ALL PATIENTS

- Must not share THALOMID capsules—especially with females of reproductive potential
- Must return any unused THALOMID capsules for disposal to Celgene or their THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to them
- Must not donate blood for 4 weeks after stopping THALOMID

FEMALE PATIENTS

- Must not get pregnant for at least 4 weeks after stopping THALOMID by using the appropriate contraceptives each time engaging in sexual activity with a male

MALE PATIENTS

- Must use a latex or synthetic condom for 4 weeks after stopping THALOMID
- Must not donate sperm for 4 weeks after stopping THALOMID

Ordering English and non-English materials

CALL CELGENE CUSTOMER CARE CENTER AT 1-888-423-5436

- Materials are available in 16 languages and include:
 - THALOMID® (thalidomide) Patient-Physician Agreement Forms
 - Patient Guide to THALOMID REMS™ Program
 - Mandatory confidential survey forms

Available languages:			
Arabic	French	Japanese	Portuguese
Cambodian	German	Korean	Russian
Chinese	Greek	Laotian	Spanish
English	Italian	Polish	Vietnamese

- THALOMID® (thalidomide) Patient-Physician Agreement Forms, Patient Guide to THALOMID REMS™ Program, and mandatory confidential survey forms requested will be faxed directly to the number you indicate. Please be prepared to provide:

Prescriber's:

Name

Identification Number

Full Address

Fax Number

Patient's:

Name

Full Address

Phone Number

Date of Birth

Identification Number

Diagnosis (most recent version of ICD code)

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of THALOMID® (thalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID to Celgene using any of the following methods.

REPORTING TO CELGENE

- Email: **drugsafety@celgene.com**
- Telephone: **1-908-673-9667**
- Toll-free: **1-800-640-7854** (Global Drug Safety & Risk Management) or **1-888-423-5436** (Celgene Customer Care Center)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online: **<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>**
- Telephone: **1-800-332-1088**
- Fax: **1-800-332-0178**
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

For more information about THALOMID® (thalidomide) and the THALOMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

THALOMID is only available under a restricted distribution program, THALOMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.



THALOMID REMS™

THALOMID®
(thali i Capsules)


THALOMID® is a registered trademark of Celgene Corporation. THALOMID REMS™ is a trademark of Celgene Corporation.

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REMS-THA13246

Reference ID: 3627000



Patient Guide to **THALOMID REMS™** Risk Evaluation and Mitigation Strategy (REMS)™ Program

This guide provides you important information about:

- The risks of THALOMID® (thalidomide)
 - Birth defects (deformed babies) or death of an unborn baby
 - Blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)
- The THALOMID REMS™ program
 - What females who can get pregnant need to know
 - Birth control options
 - What females who can not get pregnant need to know
 - What males need to know

 **THALOMID**®
(thali i Capsules

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Risks of THALOMID® (thalidomide)

THALOMID can cause harm to an unborn baby when given to a pregnant female. THALOMID causes a high frequency of severe and life-threatening birth defects (deformed babies) or death of an unborn baby, even after a single dose (1 capsule [regardless of strength]). THALOMID must not be used by pregnant females or by females who are able to get pregnant who are not using acceptable birth control or avoiding sex with a male. Females who are able to get pregnant must avoid pregnancy while taking THALOMID.

THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)



THALOMID can cause severe birth defects, including missing or severely deformed legs and arms. These babies often have hands attached directly to their shoulders and feet attached directly to their hips. Photo reprinted by permission.

What is the THALOMID REMS™ program?

To avoid serious risks to unborn babies, THALOMID is only available under a restricted distribution program called the “THALOMID Risk Evaluation and Mitigation Strategy (REMS)™” (formerly known as the *S.T.E.P.S.*® program). Only certified prescribers can prescribe THALOMID and only certified pharmacies can dispense THALOMID. In order to receive THALOMID, patients must be enrolled in the THALOMID REMS™ program and agree to follow the requirements.

For more information about THALOMID and the THALOMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center toll-free at **1-888-423-5436**.



What do all patients need to know about the THALOMID REMS™ program?

General guidelines

- This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. Just **one capsule** taken by a pregnant female can cause severe birth defects
- THALOMID® (thalidomide) does not induce abortion of the fetus and should never be used for contraception
- THALOMID must be kept out of the reach of children
- Do not open or unnecessarily handle THALOMID capsules. If a broken capsule (or the powder in the capsule) comes in contact with your skin, wash the area with soap and water
- Keep THALOMID in a cool, dry place
- Do **not** donate blood while you are taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID
- Unused THALOMID capsules should be returned for disposal to Celgene by calling **1-888-423-5436** or to your THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to you

WARNING

- **Blood clots** have been reported in patients taking THALOMID® (thalidomide), especially when used with other cancer drugs. Your healthcare provider may recommend treatment that could help prevent blood clots. Talk to your healthcare provider if you have shortness of breath, chest pains, or arm or leg swelling
- THALOMID can cause other health problems called “side effects.” For a complete listing of possible side effects, please refer to the Medication Guide
- **Be sure to report all side effects to your healthcare provider immediately.** Ask your healthcare provider about other side effects associated with THALOMID



What do females who can get pregnant need to know about the THALOMID REMS™ program?

A. Before taking THALOMID® (thalidomide)

- You must sign the THALOMID® (thalidomide) Patient-Physician Agreement Form that says you understand that THALOMID should not be used during pregnancy, and that you agree not to become pregnant while taking THALOMID
- If there is **any** chance that you can get pregnant, you must agree to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male starting at least 4 weeks **before** taking THALOMID
- Your healthcare provider must give you a pregnancy test 10 to 14 days before you receive your first prescription for THALOMID, and again within 24 hours before you receive your first prescription for THALOMID. If you are pregnant, you cannot take THALOMID
- You will have pregnancy tests before starting THALOMID and while taking THALOMID, even if you agree not to have sex with a male
- Before your healthcare provider can write your prescription for THALOMID, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies

- Before dispensing THALOMID® (thalidomide), your THALOMID REMS™ certified pharmacy will contact you to discuss treatment
- Your healthcare provider will talk with you about your birth control options

1. Choose at least 1 highly effective method and at least 1 additional effective method of birth control. Talk to your healthcare provider about the following acceptable birth control methods. See below.

Reliable Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Male latex or synthetic condom
Tubal ligation (having your tubes tied)	+ Diaphragm
Partner’s vasectomy (tying of the tubes to prevent the passing of sperm)	Cervical cap

2. Use the 2 methods of birth control at the same time

- **Remember:** You must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male. However, your healthcare provider may recommend that you use 2 different methods instead for medical reasons
- Talk to your healthcare provider to make sure that other medicines or dietary supplements you are taking do not interfere with your hormonal birth control methods
- **Remember, not having sex is the only method of birth control that is 100% effective**

3. Unacceptable methods of birth control

- Progesterone-only “mini-pills”
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield*

4. Take pregnancy tests

- You must have a pregnancy test performed by your healthcare provider 10 to 14 days before receiving your first prescription for THALOMID® (thalidomide) and again within 24 hours before receiving your first prescription for THALOMID. Both pregnancy tests must have a negative result

B. While taking THALOMID

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must talk to your healthcare provider before changing any birth control methods you have already agreed to use

*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

- You will have a pregnancy test performed by your healthcare provider:
 - Every week during the first 4 weeks of treatment, then
 - Every 4 weeks if your menstrual cycles are regular, or
 - Every 2 weeks if your cycles are irregular
 - If you miss your period or have unusual menstrual bleeding, or
 - If your medication is not dispensed within 7 days of taking the pregnancy test
- If you had sex with a male without using birth control, stop taking THALOMID® (thalidomide) immediately and call your healthcare provider right away
- If you get pregnant, or think you may be pregnant, you must **immediately** stop taking THALOMID. Contact your healthcare provider immediately to discuss your pregnancy. If you do not have an obstetrician, your healthcare provider will refer you to one for care and counseling. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must not breastfeed a baby while you are taking THALOMID
- In order to continue receiving THALOMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your THALOMID REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

C. After you have stopped taking THALOMID® (thalidomide)

- You must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male:
 - For at least 4 weeks after stopping THALOMID, or
 - Do not have any sex with a male for 4 weeks after stopping THALOMID

See also “General guidelines” on page 4 for requirements for all patients.

What do females who can not get pregnant need to know about the THALOMID REMS™ program?

A. Before taking THALOMID® (thalidomide)

- You must sign the THALOMID® (thalidomide) Patient-Physician Agreement Form that says you are currently not pregnant and are not able to get pregnant. This means that:
 - You have been in natural menopause for at least 2 years, or
 - You have had both ovaries and/or uterus removed
- For females who have not started their period (menstruation) and are under the age of 18, a parent or legal guardian must sign the THALOMID® (thalidomide) Patient-Physician Agreement Form that says the patient is not pregnant, is not able to get pregnant, and/or will not be having sex with a male for at least 4 weeks before starting THALOMID
- Before your healthcare provider can write your prescription for THALOMID, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies
- Before dispensing THALOMID, your THALOMID REMS™ certified pharmacy will contact you to discuss treatment

B. While taking THALOMID® (thalidomide)

- In order to continue receiving THALOMID, you must take part in a mandatory confidential survey every six months. You must also continue to discuss your treatment with your THALOMID REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

See also “General guidelines” on page 4 for requirements for all patients.

What do males need to know about the THALOMID REMS™ program?

- You must use a latex or synthetic condom **every time** you have sex with a female who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

A. Before taking THALOMID® (thalidomide)

- You must sign the THALOMID® (thalidomide) Patient-Physician Agreement Form. You must agree that while taking THALOMID you will use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant
- Before dispensing THALOMID, your THALOMID REMS™ certified pharmacy will contact you to discuss treatment

B. While taking THALOMID

- You must use a latex or synthetic condom **every time** (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must tell your healthcare provider right away if you have sex with a female without using a latex or synthetic condom, or if you think for any reason that your partner is or may be pregnant. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception

- You must **not** donate sperm while taking THALOMID® (thalidomide) (including during breaks [dose interruptions])
- In order to continue receiving THALOMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your THALOMID REMS™ healthcare provider. To take the survey, please go to **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**

C. After you have stopped taking THALOMID

- For 4 weeks after receiving your last dose of THALOMID, you must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- You must **not** donate sperm for 4 weeks after stopping THALOMID

See also “General guidelines” on page 4 for requirements for all patients.

Mandatory confidential patient surveys

As a patient who is enrolled in the THALOMID REMS™ program for THALOMID® (thalidomide), you will need to complete a brief mandatory confidential survey as outlined below.

Adult females who can get pregnant

- Initial survey before first prescription
- Monthly

Adult females who can not get pregnant

- Initial survey before first prescription
- Every six months

Female children

- Initial survey before first prescription
- Monthly

Males

- No initial survey
- Monthly

Mandatory confidential survey process

- When your healthcare provider tells you to take the survey, go to the patient Mandatory Confidential Survey section of **www.CelgeneRiskManagement.com** or call the Celgene Customer Care Center at **1-888-423-5436**
- Be prepared with your patient identification number
- After completing your survey, your healthcare provider will also complete a survey. Your healthcare provider will then receive authorization to write your prescription
- The prescription will be sent to a THALOMID REMS™ certified pharmacy. The THALOMID REMS™ certified pharmacy will contact you to discuss your THALOMID therapy. You will not receive your medication until you speak with the THALOMID REMS™ certified pharmacy

For more information, contact the Celgene Customer Care Center at **1-888-423-5436**
Reference ID: 3627000



A letter from the Thalidomide Victims Association of Canada (TVAC)

The following letter from the Thalidomide Victims Association of Canada (TVAC) was written in 1998 upon U.S. approval of THALOMID® (thalidomide), and is included in this brochure to be transparent about public concerns for thalidomide victims regarding the marketing of THALOMID.

Dear Doctor/Patient:

Have you ever met someone who was born disabled after exposure to thalidomide?

We have. In fact, we are thalidomiders—the name we have adopted to describe the surviving children of mothers who were prescribed thalidomide during their pregnancy as a sedative or for nausea and other symptoms of “morning sickness.”

You’ve undoubtedly seen the **dramatic photographs of babies with severe birth defects** caused when thalidomide is taken EVEN ONCE by a pregnant woman. You know the risks!

The **Thalidomide Victims Association of Canada (TVAC)** was formed to meet the needs of the approximately 125 thalidomiders alive in Canada today, and to aid the surviving 10 thalidomiders living in the United States. Of the 10,000 to 12,000 children born with thalidomide deformities around the world in the early sixties, 5,000 survive today. No one will ever know how many children were miscarried or were stillborn because of thalidomide.

TVAC exists as a survivors group to determine and find solutions to the ongoing problems we face. TVAC has also undertaken a mandate of monitoring the responsible use of thalidomide and ensuring the tragedy of the past *never happens again*.

Because of our own personal traumas, and those of our families, we have always stated that we can never accept a world with thalidomide in it.

However, as we know first-hand how people may suffer, we also concede that no one should suffer needlessly. If thalidomide can extend a life, or offer a better quality of life to people with debilitating or chronic illnesses, then we are forced to accept the fact that thalidomide use may be their choice.

As well, we are forced to prefer the regulated use of thalidomide over the alternative:

One thalidomide baby born out of ignorance is far worse than one born out of a legitimate attempt to regulate and control the distribution process of this drug.

Since you may soon be involved in prescribing or taking thalidomide, we need for you to be **fully aware of the power you have...**

- the responsibility to see that you **fully understand the risks thalidomide poses...**
- the **commitment** to do whatever it takes to make sure that NOT EVEN ONE woman loses a child due to thalidomide

We were as surprised as anyone when the people at Celgene Corporation, makers of THALOMID® (thalidomide), sought the opinions and input of those of us at TVAC concerning the use of thalidomide in the United States. We felt it was a respectful step in the right direction that our feelings, opinions, and knowledge were being considered.

We are also consoled to know that Celgene Corporation has instituted a comprehensive program to help physicians and pharmacists inform patients about side effects and risks and ensure that they are aware of precautions they must take before, during, and after therapy.

The **THALOMID Risk Evaluation and Mitigation Strategy (REMS)™** is a multifaceted program developed to help ensure that fetal exposure to THALOMID does not occur. All of the materials you need to comply with this system are enclosed.

Meanwhile, we make you one promise:

The Thalidomide Victims Association of Canada will continue to watch the progression of events where thalidomide use is concerned

We have to!

For further information regarding the history of thalidomide or the status of survivors today, please feel free to contact us.

Sincerely,



Randolph Warren
Chief Executive Office
Thalidomide Victims
Association of Canada



Giselle Cole
Past President
Thalidomide Victims
Association of Canada

Head Office

Thalidomide Victims Association of Canada

Centre Commercial Joseph Renaud
6830 Boul. Joseph Renaud, Suite 211
Montreal, Quebec, Canada
H1K 3V4

Phone: **1-514-355-0811**

Fax: **1-514-355-0860**



Warning to patients taking THALOMID® (thalidomide)

Attention females:

Do **not** take THALOMID if you are pregnant, if you are breastfeeding, or if you are able to get pregnant and are not using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.

Attention males:

You must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm).

You must **not** donate sperm while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID.

Attention all patients:

You must **not** donate blood while taking THALOMID, during breaks (dose interruptions), and for 4 weeks after stopping THALOMID.

This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. Just **one capsule** taken by a pregnant female can cause severe birth defects.

THALOMID must be kept out of the reach of children. Return any unused THALOMID capsules for disposal to Celgene by calling **1-888-423-5436**, or to your THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to you.

For more information about THALOMID® (thalidomide) and the THALOMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

THALOMID is only available under a restricted distribution program, THALOMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.



THALOMID REMS™

THALOMID®
(thali i Capsules)

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REMS-THA13247

Reference ID: 3627000



REMS Patient Survey Reminder

Patient Name _____ Date Survey Available _____

Doctor Office Contact and Phone # _____

Product _____ Pharmacy Name _____

Telephone Survey

OR

Website Survey

1	2	3
4	5	6
7	8	9
*	0	#

From a touchtone
phone dial
1-888-423-5436

Press

2

Para español, oprime
el numero dos

Press

1

to identify that you are
a patient

Press

1

to take a survey

1	2	3
4	5	6
7	8	9
*	0	#

Enter your 9-digit patient
identification number (the
number you provided during
the enrollment process – for
example your Social Security
Number).

From the menu provided, select the drug that
you have been prescribed.

Press

1

OR

Press

2

OR

Press

3

Your survey will then begin. Please answer all
of the questions. Confirmation that the survey
has been completed will be provided at the
end of your survey.

Access the internet and type in the website address
www.CelgeneRiskManagement.com

You are not required to have a User Name or Password
to complete a survey. To take your survey, left click your
mouse on the button

Patient Surveys

You will be asked for the following information. Please
enter the information exactly as it was provided during
your enrollment process

Please enter your details in the form below to continue with the patient survey.

* Patient Last Name:
* Patient First Name:
* Patient Identification Number:
Social Security Number e.g. 123456789

Please be sure to complete the survey in its entirety and upon completion send to Celgene.

After entering the information above, click

Start Survey

Survey questions will be displayed 1 per page. Please be
sure to complete the survey in its entirety. A summary
page displaying your survey answers will be displayed at
the end of your survey. Upon completion, send the survey
to Celgene by clicking

Send to Celgene

THALOMID REMS™

Program for THALOMID® (thalidomide) Education and Prescribing Safety

Dear Prescriber:

Enclosed are your THALOMID REMS™ program education materials.

Celgene Corporation is pleased to provide you with the enclosed materials for use in the THALOMID REMS™ program (formerly known as the S.T.E.P.S.® program).

Important information about the THALOMID REMS™ program

- To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called "THALOMID REMS™"
- THALOMID is contraindicated in pregnant females and females of reproductive potential who are not using acceptable contraception or continually abstaining from heterosexual sexual contact. Females of reproductive potential may be treated with THALOMID provided adequate precautions are taken to avoid pregnancy
- Male Patients: Thalidomide is present in semen. Male patients taking THALOMID should not donate sperm. Males receiving THALOMID must always use a latex or synthetic condom during any sexual contact with females of reproductive potential even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with THALOMID REMS™ can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS™ program

As a prescriber certified with the THALOMID REMS™ program, please review and familiarize yourself with the contents of the enclosed THALOMID REMS™ Kit:

Prescriber Materials

- THALOMID REMS™ software and Installation Guide
- Prescriber Guide to the THALOMID REMS™ Program
- THALOMID Full Prescribing Information

Patient Materials (Patient Resource Pack)

- Patient Guide to THALOMID REMS™ Program
- Emergency Contraception Brochure
- MEDICATION GUIDE

To order additional Patient Resource Packs, or if you have any questions about using the enclosed software, please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,



Jerome B. Zeldis, MD, PhD
Chief Medical Officer

Risks of THALOMID® (thalidomide)

- If THALOMID is used during pregnancy, it can cause birth defects or embryo-fetal death. THALOMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking THALOMID
- THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

THALOMID in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma. The effectiveness of THALOMID is based on response rates (see CLINICAL STUDIES section). There are no controlled trials demonstrating a clinical benefit, such as an improvement in survival.

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.



THALOMID REMS™

THALOMID®
(thali i Capsules)

THALOMID® is a registered trademark of Celgene Corporation. THALOMID REMS™ is a trademark of Celgene Corporation.

THALOMID REMS™

At-A-Glance

Important information about THALOMID® (thalidomide) and the THALOMID Risk Evaluation and Mitigation Strategy (REMS)™ program

- THALOMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called “THALOMID REMS™” (formerly known as the S.T.E.P.S.® program)
- Only prescribers and pharmacies certified by the THALOMID REMS™ program can prescribe and dispense THALOMID to patients who are enrolled and meet all the conditions of the THALOMID REMS™ program
- Information about THALOMID and the THALOMID REMS™ program can be obtained by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center toll-free at 1-888-423-5436

For more information about THALOMID and the THALOMID REMS™ program, please visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-423-5436.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.



THALOMID REMS™

THALOMID®
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Initial prescription (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain 2 negative pregnancy tests sensitive to at least 50 mIU/mL, even if continuous abstinence is the chosen method of birth control. One test must be obtained 10 to 14 days and one test within 24 hours prior to writing an initial prescription for THALOMID® (thalidomide).
2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open THALOMID capsules and to maintain storage of capsules in blister packs until ingestion.
3. Obtain, review, and complete the THALOMID® (thalidomide) Patient-Physician Agreement Form online at www.CelgeneRiskManagement.com, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**.

- **Males (adults and children)**

- **Females of reproductive potential include all females who are menstruating**, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category

- **Females not of reproductive potential include females who have been in natural menopause for at least 24 consecutive months**, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating

4. Send the completed and signed THALOMID® (thalidomide) Patient-Physician Agreement Form online through www.CelgeneRiskManagement.com, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**.
5. Instruct female patients to complete a brief initial mandatory confidential survey at www.CelgeneRiskManagement.com, or by calling **1-888-423-5436**, prior to prescriber obtaining an authorization number.

- Males do not need to complete the initial survey

6. Complete a prescriber brief mandatory confidential survey by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written.

- You will need to enter the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)

7. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.

8. Send the prescription to a certified pharmacy.

Subsequent prescriptions (for all patients unless otherwise noted)

1. For females of reproductive potential, obtain scheduled pregnancy tests weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks.

2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open THALOMID capsules and to maintain storage of capsules in blister packs until ingestion.

3. Instruct patient to complete a brief mandatory confidential survey **as scheduled**, prior to prescriber obtaining an authorization number and filling the prescription.

- Monthly:

- **Males (adults and children)**
- **Females of reproductive potential (adults and children)**
- **Female children not of reproductive potential**

- Every 6 months:

- **Adult females not of reproductive potential**

4. Complete a prescriber brief mandatory confidential survey by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center at **1-888-423-5436**, for every patient before each prescription is written.

- You will need to enter the following information:

- Prescriber's identification number
- Patient's identification number
- Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
- Average daily dose
- Total number of days supplied (cannot exceed 28 days)

5. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.

6. Send the prescription to a certified pharmacy.

THALOMID REMS™

Prescriber Enrollment Form

All prescribers must be certified to prescribe THALOMID® (thalidomide). To become certified the prescriber must:

1. Complete the Prescriber Enrollment Form, which is required for THALOMID REMS™ (formerly known as the S.T.E.P.S.® program) certification.
2. Agree to steps on the following page that must be followed with every patient.

To submit this form electronically, please go to www.CelgeneRiskManagement.com.

To submit this form via fax, please complete the following page and fax it to 1-888-432-9325.

THALOMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID provided adequate precautions are taken to avoid pregnancy.

Please review the steps on the following page that must be followed with every patient.

THALOMID is only available under a restricted distribution program, THALOMID REMS™.

 **THALOMID**[®]
(thali i Capsules

THALOMID REMS™ Prescriber Enrollment Form

When prescribing THALOMID® (thalidomide), I agree to:

- Provide patient counseling on the benefits and risks of THALOMID therapy, including Boxed Warnings
- Submit a completed THALOMID® (thalidomide) Patient-Physician Agreement Form for each new patient
- Provide contraception and emergency contraception counseling with each new prescription prior to and during THALOMID treatment
- Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions
- Report any pregnancies in female patients or female partners of male patients prescribed THALOMID immediately to Celgene Drug Safety (or Celgene Customer Care Center)
- Complete a mandatory and confidential prescriber survey online or by telephone for all patients and obtain a new authorization number for each prescription written and include this authorization number on the prescription
- Facilitate female patient compliance with an initial mandatory confidential patient survey online or by telephone
- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- Contact a THALOMID REMS™ certified pharmacy to fill the prescription
- Return to Celgene all THALOMID capsules that are returned by patients. Shipping fees will be paid by Celgene Corporation. To arrange returns, call the Celgene Customer Care Center
- Remind patients to return all THALOMID capsules to Celgene Corporation or their THALOMID prescriber, or to the pharmacy that dispensed the THALOMID to them
- Re-enroll patients in the THALOMID REMS™ program if THALOMID is required and previous therapy with THALOMID has been discontinued for 12 consecutive months

Please fill out the spaces below completely.

Prescriber Name _____

Degree: MD/DO/PA/NP/Fellow/Medical Resident _____

Specialty _____

Prescriber Identification Number (eg, DEA Number, Social Security Number, NPI Number, etc.) _____

Please indicate which office(s) will receive THALOMID REMS™ materials and updates:

☐ Primary Office Name _____

Attention _____

Address _____

City _____ State _____ ZIP Code _____

Phone _____ Ext. _____ Fax _____

Email Address _____

☐ Secondary Office Name _____

Attention _____

Address _____

City _____ State _____ ZIP Code _____

Phone _____ Ext. _____ Fax _____

Email Address _____

I understand that if I fail to comply with all requirements of the THALOMID REMS™ program, my prescriptions for THALOMID® (thalidomide) will not be honored at certified pharmacies.

Prescriber Signature _____ Date _____

Return this form to the Celgene Customer Care Center via fax or mail.

Mail to: Celgene Customer Care Center, 86 Morris Avenue, Summit, NJ 07901

Phone: **1-888-423-5436**

Fax: **1-888-432-9325**

www.CelgeneRiskManagement.com



THALOMID REMS™

THALOMID®
(thali i Capsules)

THALOMID REMS[™]

THALOMID Risk Evaluation and Mitigation Strategy (REMS)[™]
program education and prescribing safety kit

Risks of THALOMID[®] (thalidomide)

- If THALOMID is used during pregnancy, it can cause birth defects or embryo-fetal death. THALOMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking THALOMID
- THALOMID causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

THALOMID in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma (MM).

THALOMID is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL).

THALOMID is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

THALOMID is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.



THALOMID REMS™

Prescriber quick reference guide

1. The prescriber provides comprehensive counseling.
2. The prescriber verifies negative pregnancy test for all female patients of reproductive potential.
3. The prescriber completes THALOMID® (thalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene.
4. Female patients complete initial mandatory confidential survey by:
 - Visiting **www.CelgeneRiskManagement.com**, or
 - Calling Celgene Customer Care Center at **1-888-423-5436**

Male patients do not need to complete the initial survey.

All patients must complete subsequent mandatory confidential surveys as outlined in the Prescriber Guide to THALOMID REMS™ Program (formerly known as the S.T.E.P.S.® program).

5. The prescriber completes mandatory confidential survey and receives authorization number by:
 - Visiting **www.CelgeneRiskManagement.com**, or
 - Calling Celgene Customer Care Center at **1-888-423-5436**
6. The prescriber writes THALOMID prescription and includes authorization number and patient risk category.
7. The prescriber sends prescription to certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the THALOMID REMS™ procedures.

THALOMID is only available under a restricted distribution program, THALOMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.



THALOMID REMS™

THALOMID®
(thali i Capsules

Pharmacy Guide to **THALOMID REMS™**

Risk Evaluation and Mitigation Strategy (REMS)™ Program



Important information about THALOMID® (thalidomide) and the THALOMID REMS™ program

- THALOMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with THALOMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, THALOMID is only available under a restricted distribution program called “THALOMID REMS™” (formerly known as the *S.T.E.P.S.*® program)
- Only prescribers and pharmacies certified with the THALOMID REMS™ program can prescribe and dispense the product to patients who are enrolled and meet all the conditions of the THALOMID REMS™ program
- Dispensing pharmacists must be educated on the THALOMID REMS™ program and on dispensing procedures for THALOMID
- Information about THALOMID and the THALOMID REMS™ program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**

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Guidelines for ordering, counseling, and dispensing THALOMID® (thalidomide)

Dispensing pharmacies must be certified in the THALOMID REMS™ program with Celgene and must be educated in the following dispensing procedures.

Step 1. Review incoming THALOMID prescriptions

- A. Only accept prescriptions with an authorization number and patient risk category written on them.
- Authorization numbers are valid for 7 days from the date of last pregnancy test for female patients of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted
 - Faxed prescriptions are permissible depending on state laws
- B. Make sure the prescription is signed and dated.
- C. Confirm the prescription is written for a 4-week (28-day) supply or less.
- D. For subsequent prescriptions, verify there are 7 days or less remaining of therapy on the existing prescription.

Step 2. Counsel patients

- A. Make sure a **certified THALOMID REMS™** counselor counsels the patient.
- B. Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist and ensure the form is signed and dated. Ensure the appropriate boxes are checked off. Retain a copy of the checklist and record of the associated prescription.
- C. If the patient mentions adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID, make sure to document these experiences using acceptable documentation as noted on the checklist.
- **Acceptable documentation examples:**
 1. Celgene Adverse Drug Event form and fax confirmation
 2. Pharmacy log
- D. Report adverse drug experiences that are suspected to be associated with the use of THALOMID to Celgene Drug Safety within 24 hours. See the Adverse Drug Experience Reporting Procedure on page 7 for more information.

Guidelines for ordering, counseling, and dispensing THALOMID® (thalidomide) (continued)

Step 3. Obtain confirmation number from Celgene Customer Care

A. Prior to each prescription, contact Celgene Customer Care at **1-888-423-5436**, available 24 hours a day, 7 days a week. Eligible pharmacies may also use the Celgene REMS Pharmacy Portal at **www.CelgeneREMSPharmacyPortal.com**. Call your Celgene Account Manager to see if your pharmacy is eligible.

- Enter the pharmacy NABP number or DEA number
- Enter the authorization number written on the prescription
- Enter the number of capsules and milligram strength being dispensed

B. Write the confirmation number and the date of receipt on the prescription. The confirmation number is only valid for 24 hours.

C. If you do not obtain a confirmation number, do not dispense THALOMID.

Step 4. Dispensing

A. No Refills. A new prescription is required for each dispense. **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription.**

B. Ensure the confirmation number has not expired, ie, dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **Do Not Dispense**. You must call Celgene Customer Care at **1-888-423-5436** to cancel the first confirmation number and obtain a new confirmation number. For female patients of reproductive potential, ship the same day or hand to the patient within 24 hours.

C. Dispense each prescription with a Medication Guide and maintain a record on acceptable documentation.

Acceptable documentation examples:

1. Signed Education and Counseling Checklist (if counseling pharmacist and dispensing pharmacist are the same)
2. Pharmacy log

Guidelines for ordering, counseling, and dispensing THALOMID® (thalidomide) (continued)

D. Document the dispense date and maintain a record on acceptable documentation.

Acceptable documentation examples:

1. Shipping receipt
2. Pharmacy dispensing log

E. Dispense no more than a 4-week (28-day) supply. A new prescription is required for each dispense. No automatic refills or telephone prescriptions are permitted.

F. A signature is required for all shipping and dispense if picked up by patient.

Step 5. Perform drug accountability

A. Pharmacy shall keep an inventory log for THALOMID, by strength, reflecting its on-hand inventory at all times.

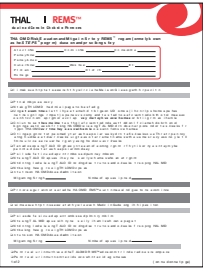
B. Do not transfer THALOMID to another pharmacy without prior authorization from Celgene.

C. Accept unused THALOMID (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal.

THALOMID Risk Evaluation and Mitigation Strategy (REMS)™ Education and Counseling Checklist for Pharmacies

Ensure your patients know the risks

Before you are able to fill a prescription for THALOMID® (thalidomide), a checklist for each patient must be completed based on the patient risk category (written on the front of the Patient Prescription Form). When completing the checklist, be sure all the appropriate boxes are checked off (✓) and the form is signed and dated. All boxes and spaces must be marked or filled in during counseling with the patient for every prescription. Retain a copy of the checklist and record of the associated prescription.



Be prepared to provide the following information for each checklist:

Authorization Number	Confirmation Number	Confirmation Date
Pharmacy Name	Pharmacy Address (including City, State, ZIP Code)	
Counselor Name	Work Phone Number	Extension
Patient Name	Patient Date of Birth	

Rules for dispensing and shipping

Making sure before you release THALOMID

DO NOT DISPENSE OR SHIP THALOMID TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:

- Prescription has an authorization number and patient risk category written on it
- You have obtained a confirmation number and a confirmation date
- You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained
- The Medication Guide is included with the prescription
- You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing THALOMID prescription

For further information about THALOMID, please refer to the full Prescribing Information, enclosed.

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of THALOMID® (thalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID to Celgene using any of the following methods.

REPORTING TO CELGENE

- Email: **drugsafety@celgene.com**
- Telephone: **1-908-673-9667**
- Toll-free: **1-800-640-7854** (Global Drug Safety & Risk Management) or **1-888-423-5436** (Celgene Customer Care Center)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of THALOMID and any suspected pregnancy occurring during the treatment with THALOMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online at: **<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>**
- Telephone: **1-800-332-1088**
- Fax: **1-800-332-0178**
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

For more information about THALOMID® (thalidomide) and the THALOMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

THALOMID is only available under a restricted distribution program, THALOMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.



THALOMID REMS™

 **THALOMID**
(thali i Capsules

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REMS-THA13275

THALOMID REMS™

Education and Counseling Checklist for Pharmacies

THALOMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the S.T.E.P.S.® program) education and prescribing safety

Authorization No.: _____ Confirmation No.: _____ Confirmation Date: _____
Pharmacy Name: _____
Pharmacy Address: _____
Counselor Name: _____ Work Phone: _____ Ext.: _____
Patient Name: _____ Date of Birth: _____
Risk Category: _____

Checklist for female patients of reproductive potential

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Potential embryo-fetal toxicity
- ☐ Not taking THALOMID® (thalidomide) if pregnant or breastfeeding
- ☐ Using **at the same time** at least 1 highly effective method—tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—**every time they have sex with a male**, or abstaining from sex with a male
- ☐ Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking THALOMID, while taking THALOMID, during dose interruptions, and for at least 4 weeks after stopping THALOMID **every time they have sex with a male**, or abstaining from sex with a male
- ☐ Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- ☐ The need to stop taking THALOMID right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately
- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing THALOMID capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID
- ☐ Not breaking, chewing, or opening THALOMID capsules
- ☐ Instructions on THALOMID dose and administration

Milligram (mg) Strength _____

Number of Capsules Dispensed _____

FEMALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the THALOMID REMS™ education material and agreed to ensure compliance

Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing THALOMID capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID
- ☐ Not breaking, chewing, or opening THALOMID capsules
- ☐ Instructions on THALOMID dose and administration

Milligram (mg) Strength _____

Number of Capsules Dispensed _____

FEMALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the THALOMID REMS™ education material and agreed to ensure compliance
- ☐ Parent or legal guardian must inform the child's doctor when the child begins menses

Checklist for male patients

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

I COUNSELED ADULTS AND CHILDREN ON:

- ☐ Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom **every time** when engaging in sexual intercourse with a female who can get pregnant)
- ☐ Female partners of males taking THALOMID® (thalidomide) must call their healthcare provider right away if they get pregnant
- ☐ Possible side effects include deep vein thrombosis and pulmonary embolism
- ☐ Not sharing THALOMID capsules with anyone—especially with females who can get pregnant
- ☐ Not donating blood or sperm while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID
- ☐ Not breaking, chewing, or opening THALOMID capsules
- ☐ Instructions on THALOMID dose and administration

Milligram (mg) Strength _____

Number of Capsules Dispensed _____

MALE CHILDREN (<18 YEARS OF AGE):

- ☐ Parent or legal guardian must have read the THALOMID REMS™ education material and agreed to ensure compliance

All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.

Counselor Signature: _____ **Date:** _____

For more information about THALOMID and the THALOMID REMS™ program, please visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation
86 Morris Ave
Summit, NJ 07901

THALOMID is only available under a restricted distribution program, THALOMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.



THALOMID REMS™

THALOMID®
(thali i Capsules)

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REMS-THA13346

Celgene REMS Programs Pharmacy Training: THALOMID REMS™

Section 1: What Is a REMS?



In this section



- What is a REMS?
- Celgene REMS programs
- Pharmacy staff knowledge check

What is a REMS?



- REMS stands for **Risk Evaluation and Mitigation Strategies**
- REMS programs are mandated by the **US Food and Drug Administration (FDA)**
- According to the FDA, a REMS program is:
 - A strategy to manage a known or potential serious risk associated with a drug or biological product
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

Celgene REMS programs



- Celgene has REMS programs for THALOMID[®] (thalidomide), REVLIMID[®] (lenalidomide), and POMALYST[®] (pomalidomide):
 - THALOMID REMS[™] program (formerly known as the S.T.E.P.S.[®] program) for THALOMID
 - REVLIMID REMS[™] program (formerly known as the RevAssist[®] program) for REVLIMID
 - POMALYST REMS[™] for POMALYST
- If these treatments are used during pregnancy, they can cause serious birth defects or embryo-fetal death
- The goals of these REMS programs are:
 - To prevent the risk of embryo-fetal exposure to these treatments
 - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment

Celgene REMS programs (continued)



For more information on Celgene REMS programs:

- Call Celgene Customer Care at 1-888-423-5436
- Visit the specific product website

Did you know?

Celgene Customer Care has Compliance Specialists to educate and train pharmacy staff on Celgene REMS program guidelines and compliance.

Pharmacy staff knowledge check



- REMS stands for Risk Evaluation and Mitigation Strategies.
 - A. True
 - B. False

Correct Answer: A. True

- REMS stands for **Risk Evaluation and Mitigation Strategies**
- A REMS is a strategy to manage a known or potential serious risk associated with a drug or biological product

Pharmacy staff knowledge check (continued)



- Who mandates REMS programs?
 - A. Celgene
 - B. The FDA
 - C. The EPA

Correct Answer: B. The FDA

- REMS programs are mandated by the FDA
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

Pharmacy staff knowledge check (continued)



- Celgene REMS programs are mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment.
 - A. True
 - B. False

Correct Answer: A. True

- The goals of the Celgene REMS programs are:
 - To prevent the risk of embryo-fetal exposure to these treatments
 - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment

Celgene REMS Programs Pharmacy Training: THALOMID REMS™

Section 2: Program Requirements for Patients and Prescribers

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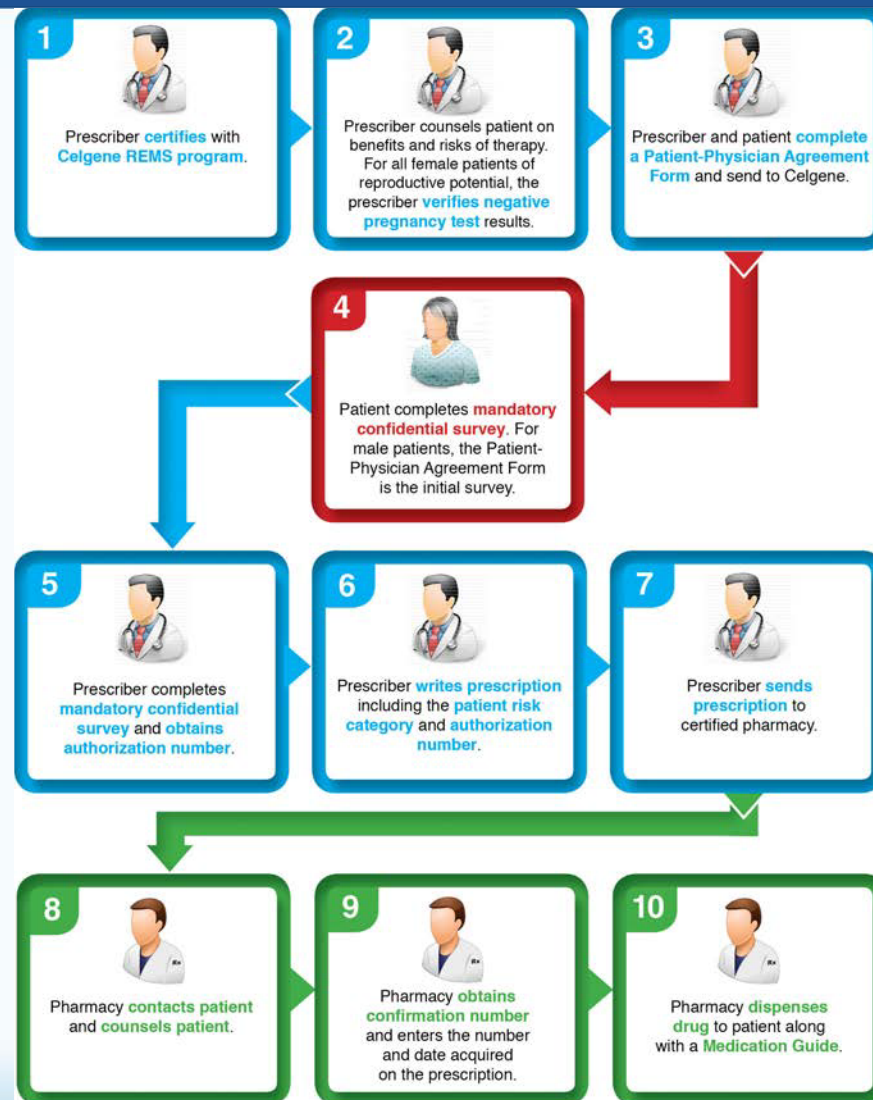


In this section



- Program overview
- Certification and enrollment requirements for prescribers and patients
- Patient risk categories
- Contraception requirements
- Pregnancy test requirements
- Mandatory confidential surveys
- Pharmacy staff knowledge check

Celgene REMS program overview



Certification and enrollment requirements for prescribers and patients



- Prescribers must be certified with the Celgene REMS program in order to prescribe a product with a REMS program for a patient
 - Prescribers must complete the REMS program enrollment and agree to comply with the program requirements
- Prescribers are required to enroll patients in a specific Celgene REMS program before starting a patient on a therapy with a REMS
 - Patients must enroll in the REMS program and agree to comply with the program requirements

Patient risk categories



- There are 6 different patient risk categories for patients enrolled in Celgene REMS programs:
 - Adult female of reproductive potential
 - Female child of reproductive potential
 - Adult female not of reproductive potential
 - Female child not of reproductive potential
 - Adult male
 - Male child

Definition of females of reproductive potential



Females of reproductive potential include all females who:

- Are menstruating
- Are amenorrheic from previous medical treatments
- Are under 50 years of age
- Are perimenopausal
- Do not qualify for the females not of reproductive potential category

The risk categories for **females of reproductive potential** are:

- Adult female of reproductive potential
- Female child of reproductive potential

Definition of females not of reproductive potential



Females not of reproductive potential include females who:

- Have been in natural menopause for at least 24 consecutive months
- Have had a hysterectomy and/or bilateral oophorectomy
- Have not started menstruating

The risk categories for **females not of reproductive potential** are:

- Adult female not of reproductive potential
- Female child not of reproductive potential

Definition of males



Males include adults and children (under 18 years of age)

The risk categories for **males** are:

- Adult Male
- Male Child

Contraception requirements: Females of reproductive potential



- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include using at the same time **at least 1 highly effective method** and **at least 1 additional method** of birth control every time they have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

Highly effective methods

Tubal ligation

Intrauterine device (IUD)

Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)

Partner's vasectomy

Additional effective methods

Male latex or synthetic condom

Diaphragm

Cervical cap

Remind patients that not having any sexual intercourse is the only birth control method that is **100% effective**.

Contraception requirements: Females of reproductive potential (continued)



- **Unacceptable contraception methods:**
 - Progesterone-only “mini-pills”
 - IUD Progesterone T
 - Female condoms
 - Natural family planning (rhythm method) or breastfeeding
 - Fertility awareness
 - Withdrawal
 - Cervical shield
 - A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception

Contraception requirements:

Males



- Male patients must use a latex or synthetic condom:
 - Every time they have sexual intercourse with a female of reproductive potential
 - Even if they have undergone a successful vasectomy
 - During therapy (including dose interruptions)
 - For 4 weeks after discontinuation of therapy

Remind patients that not having any sexual intercourse is the only birth control method that is **100% effective**.

Pregnancy test requirements



- For females of reproductive potential, prescriber must obtain a negative pregnancy test:
 - 10 to 14 days before an initial prescription
 - Within 24 hours before an initial prescription
 - The pregnancy test must be sensitive to at least 50 mIU/mL
- Subsequent pregnancy testing should occur:
 - Weekly during the first 4 weeks of use, then
 - Every 4 weeks if patient has regular menses or no menses, or
 - Every 2 weeks if irregular menses

Pregnancy test requirements (continued)



If pregnancy does occur:

- Treatment must be **immediately** discontinued
- Any suspected embryo-fetal exposure must be reported **immediately** to Celgene Global Drug Safety and reported to the FDA
 - Celgene Global Drug Safety: 1-800-640-7854
 - FDA MedWatch number: 1-800-332-1088
- The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling

Mandatory confidential surveys



- All patients must complete brief mandatory confidential surveys in order to obtain treatment
 - Surveys can be completed via CelgeneRiskManagement.com or by calling Celgene Customer Care at 1-888-423-5436

Patient Mandatory Confidential Survey Schedule for Adults and Children

Risk category	Initial Prescription	Subsequent Prescriptions
Females of reproductive potential	Complete appropriate survey	Monthly survey
Females not of reproductive potential	Complete appropriate survey	Child: Monthly survey Adult: Survey every 6 months
Males	Do not need to take initial survey	Monthly survey

Pharmacy staff knowledge check



- How many patient risk categories are there in the Celgene REMS programs?
 - A. 3
 - B. 5
 - C. 6

Correct Answer: C. 6

Celgene REMS program patient risk categories	
Adult	Child (under 18)
Adult female of reproductive potential	Female child of reproductive potential
Adult female not of reproductive potential	Female child not of reproductive potential
Adult male	Male child

Pharmacy staff knowledge check (continued)



- For all Celgene REMS products, female patients of reproductive potential must take a pregnancy test:
 - A. 10-14 days before first prescription
 - B. Within 24 hours before first prescription
 - C. 10-14 days and within 24 hours before first prescription

Correct Answer:

C. 10-14 days and within 24 hours before first prescription

- Prescribers must obtain 2 negative pregnancy tests before the first prescription for females of reproductive potential:
 - 10 to 14 days before an initial prescription
 - Within 24 hours before an initial prescription

Pharmacy staff knowledge check (continued)



- Which is a **highly effective** method of contraception?
 - A. Male latex or synthetic condom
 - B. IUD
 - C. Female condom

Correct Answer: B. IUD

Highly effective methods	Additional effective methods
Tubal ligation	Male latex or synthetic condom
Intrauterine device (IUD)	Diaphragm
Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Cervical cap
Partner's vasectomy	

Celgene REMS Programs Pharmacy Training: THALOMID REMS™

Section 3: Program Requirements for Pharmacies

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In this section



- Training and certification requirements
- Pharmacy compliance
- Pharmacy staff knowledge check

Training and certification requirements



- Celgene REMS program certified counselors must:
 - Be licensed healthcare professionals
 - Complete the Celgene-sponsored training on all required modules **annually** and pass certification exam **with 100% accuracy**
 - Educate patient by telephone or in person before treatment can be dispensed
 - Understand and counsel patients on the potential for birth defects or death to an unborn baby
 - Counsel patients on possible side effects
- Other pharmacy staff involved in dispensing treatment must:
 - Be educated on the guidelines for dispensing

Pharmacy compliance



- Pharmacy manager responsibilities
 - Educate all staff regarding dispensing guidelines
 - Includes floater pharmacists, pharmacy technicians, or anyone else handling the product
 - Make sure counselors are registered and certified in ComplianceWire® and advise Celgene of inactive counselors
 - Complete and return all documentation that pertains to non-compliance

Did you know? Pharmacy managers can call Celgene Customer Care at **1-888-423-5436** with questions. Ask for Risk Compliance.

Pharmacy compliance (continued)



- Pharmacy deviations
 - The pharmacy will be required to investigate and correct conditions that lead to deviations from Celgene REMS programs
 - Celgene will work with the pharmacy to implement appropriate corrective actions and a timeframe for those actions
 - If corrective actions are not successful, Celgene may take additional action, up to and including deactivation of the pharmacy

Pharmacy compliance (continued)



- A High Risk Deviation is:
 - Any action taken by the pharmacy that is inconsistent or non-compliant with the Celgene REMS program that increases the risk of embryo-fetal exposure
 - Any action that occurs on a consistent basis that shows a pharmacy's negligent or willful disregard to the Celgene REMS program requirements
- If there are 3 High Risk Deviations within 1 year, the pharmacy will be deactivated and will no longer be permitted to dispense product

Pharmacy staff knowledge check



- Celgene REMS program certified counselors must complete the Celgene-sponsored training:
 - A. Annually
 - B. Every 6 months
 - C. Every 2 years

Correct Answer: A. Annually

- Counselors must complete the Celgene-sponsored training annually

Pharmacy staff knowledge check (continued)



- All counselors must pass the certification test with an accuracy of:
 - A. 100%
 - B. 90%
 - C. 95%

Correct Answer: A. 100%

- Counselors must pass the certification exam with 100% accuracy

Pharmacy staff knowledge check (continued)



- Celgene may deactivate pharmacies for deviations.
 - A. True
 - B. False

Correct Answer: A. True

- The pharmacy will be required to investigate and correct conditions that lead to deviations from Celgene REMS programs
- If corrective actions are not successful, Celgene may take additional action, up to and including deactivation of the pharmacy

Celgene REMS Programs Pharmacy Training: THALOMID REMS™

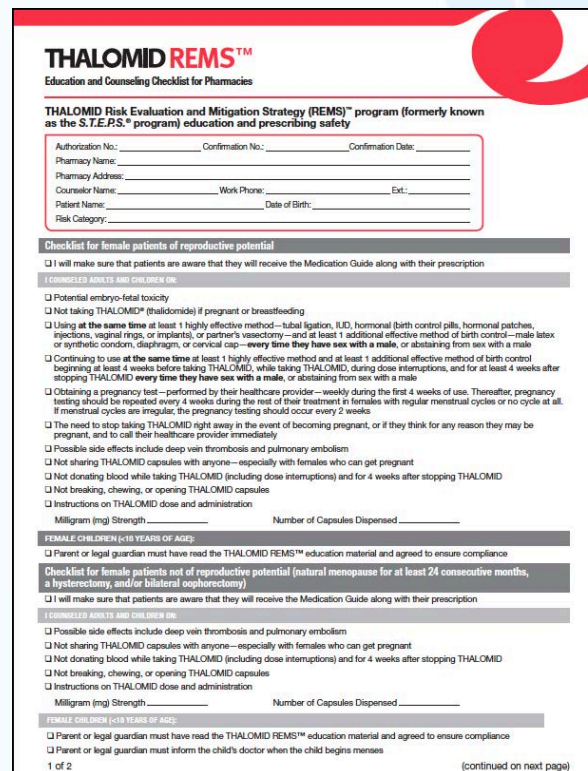
Section 4: Guidelines for Counseling

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In this section

- Counseling for female patients of reproductive potential
- Counseling for female patients not of reproductive potential
- Counseling for male patients
- Additional counseling for all patients taking THALOMID® (thalidomide)
- Pharmacy staff knowledge check



THALOMID REMS™
Education and Counseling Checklist for Pharmacies

THALOMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the S.T.E.P.S.™ program) education and prescribing safety

Authorization No.: _____ Confirmation No.: _____ Confirmation Date: _____
Pharmacy Name: _____
Pharmacy Address: _____
Counselor Name: _____ Work Phone: _____ Ext.: _____
Patient Name: _____ Date of Birth: _____
Risk Category: _____

Checklist for female patients of reproductive potential

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

FOR UNPREGNANT ADULTS AND CHILDREN ONLY

☐ Potential embryo-fetal toxicity

☐ Not taking THALOMID® (thalidomide) if pregnant or breastfeeding

☐ Using at the same time at least 1 highly effective method—tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condoms, diaphragms, or cervical cap—every time they have sex with a male, or abstaining from sex with a male

☐ Continuing to use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking THALOMID, while taking THALOMID, during dose interruptions, and for at least 4 weeks after stopping THALOMID every time they have sex with a male, or abstaining from sex with a male

☐ Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks

☐ The need to stop taking THALOMID right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately

☐ Possible side effects include deep vein thrombosis and pulmonary embolism

☐ Not sharing THALOMID capsules with anyone—especially with females who can get pregnant

☐ Not donating blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

☐ Not breaking, chewing, or opening THALOMID capsules

☐ Instructions on THALOMID dose and administration

Milligram (mg) Strength: _____ Number of Capsules Dispensed: _____

FEMALE CHILDREN (18 YEARS OF AGE)

☐ Parent or legal guardian must have read the THALOMID REMS™ education material and agreed to ensure compliance

Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy)

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription

FOR UNPREGNANT ADULTS AND CHILDREN ONLY

☐ Possible side effects include deep vein thrombosis and pulmonary embolism

☐ Not sharing THALOMID capsules with anyone—especially with females who can get pregnant

☐ Not donating blood while taking THALOMID (including dose interruptions) and for 4 weeks after stopping THALOMID

☐ Not breaking, chewing, or opening THALOMID capsules

☐ Instructions on THALOMID dose and administration

Milligram (mg) Strength: _____ Number of Capsules Dispensed: _____

FEMALE CHILDREN (18 YEARS OF AGE)

☐ Parent or legal guardian must have read the THALOMID REMS™ education material and agreed to ensure compliance

☐ Parent or legal guardian must inform the child's doctor when the child begins menses

1 of 2 (continued on next page)

The sequence of this section is based on the Education and Counseling Checklist for Pharmacies.

Remember to fill out this checklist for every patient for every prescription.

Counseling for female patients of reproductive potential



- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

COUNSEL ADULTS AND CHILDREN ON:

- Potential embryo-fetal toxicity
- Not taking treatment if pregnant or breastfeeding
- Using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time they have sex with a male**, or abstaining from sex with a male
 - **Highly effective** methods of contraception: Tubal ligation, intrauterine device (IUD), hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy
 - **Additional effective** methods of contraception: Male latex or synthetic condom, diaphragm, or cervical cap

Counseling for female patients of reproductive potential (continued)



COUNSEL ADULTS AND CHILDREN ON:

- Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control:
 - Beginning at least 4 weeks before treatment
 - During treatment
 - During dose interruptions
 - For at least 4 weeks after stopping treatment
 - **Every time they have sex with a male**, or abstaining from sex with a male

Counseling for female patients of reproductive potential (continued)



COUNSEL ADULTS AND CHILDREN ON:

- Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use
 - Pregnancy testing should be repeated:
 - Every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all
 - If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- The need to stop treatment right away **in the event of becoming pregnant, or if they think for any reason they may be pregnant**, and to call their healthcare provider immediately

Counseling for female patients of reproductive potential (continued)



COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
 - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

FOR FEMALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance

Counseling for female patients not of reproductive potential



- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
 - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

Counseling for female patients not of reproductive potential (continued)



FOR FEMALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance
- Parent or legal guardian must inform the child's doctor when the child begins menses

Counseling for male patients



- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

COUNSEL ADULTS AND CHILDREN ON:

- Potential embryo-fetal toxicity and contraception
 - Wearing a latex or synthetic condom every time when engaging in sexual intercourse with a female who can get pregnant
- Female partners of males receiving treatment must call their healthcare provider right away if they get pregnant

Counseling for male patients (continued)



COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone—especially with females who can get pregnant
- Not donating blood or sperm during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
 - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

FOR MALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance

Additional counseling for all patients taking THALOMID® (thalidomide)



COUNSEL ADULTS AND CHILDREN ON:

- Possible side effects include deep vein thrombosis and pulmonary embolism

Counsel patient to **contact healthcare provider** if experiencing any side effects.

Pharmacy staff knowledge check



- Which of these is **not** something patients need to be counseled on?
 - A. Not sharing capsules
 - B. Not breaking, chewing, or opening capsules
 - C. Wearing gloves while taking capsules

Correct Answer: C. Wearing gloves while taking capsules.

- Patients must be counseled on:
 - Not sharing capsules with anyone—especially with females who can get pregnant
 - Not breaking, chewing, or opening capsules

Pharmacy staff knowledge check (continued)



- Female patients of reproductive potential must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control for 4 weeks after stopping treatment.
 - A. True
 - B. False

Correct Answer: A. True

- Female patients of reproductive potential must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control:
 - Beginning at least 4 weeks before treatment
 - During treatment
 - During dose interruptions
 - For at least 4 weeks after stopping treatment
 - **Every time they have sex with a male**, or abstaining from sex with a male

Pharmacy staff knowledge check (continued)



- All patients must receive a Medication Guide along with their prescription.
 - A. True
 - B. False

Correct Answer: A. True

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

Celgene REMS Programs Pharmacy Training: THALOMID REMS™

Section 5: Guidelines for Dispensing

Celgene Confidential: For Celgene Business Use Only



In this section



- Pharmacy and prescription requirements
- Dispensing guidelines
- Steps for dispensing
- Pharmacy staff knowledge check

Pharmacy and prescription requirements



- Dispensing pharmacies must be certified in the applicable Celgene REMS program and educated on the program and on dispensing procedures for the treatment
- Pharmacy must ensure that every prescription includes:
 - Patient and prescriber demographics and contact information
 - Patient risk category
 - Dosing information and instructions
 - Authorization number
 - Prescriber signature
- Authorization numbers are valid for **7 days** from the date of last pregnancy test for female patients of reproductive potential and **30 days** from the date it is issued for all other patients
- No automatic refills or telephone prescriptions are permitted
- Faxed prescriptions are permissible depending on state laws

Dispensing guidelines



- Dispense **no more than a 4-week (28-day) supply** with the Medication Guide. A new prescription is required for further dispensing
- **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription**
- Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
- For females of reproductive potential, product **must be shipped the same day** confirmation number is obtained **or picked-up within 24 hours** of obtaining confirmation
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame
 - Pharmacy must obtain a new confirmation number by calling Celgene Customer Care at 1-888-423-5436 when ready to ship or have the product picked-up

Dispensing guidelines (continued)



- When shipping, pharmacy must require a signature confirming receipt
- Pharmacy shall keep an inventory log for the drug, by strength, reflecting its on-hand inventory at all times
- Do not transfer the drug to another pharmacy without prior authorization from Celgene
- Accept unused capsules (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal

Steps for dispensing



Review incoming prescriptions

- Only accept prescriptions with all of the following information:
 - Patient and prescriber demographics and contact information
 - Patient risk category
 - Dosing information and instructions
 - Authorization number
 - Prescriber signature
- Make sure the prescription is signed and dated
- Confirm the prescription is written for a 4-week (28-day) supply or less
- For subsequent prescriptions, verify there are 7 days or less of therapy remaining on the existing prescription

Steps for dispensing (continued)



Counsel patient

- Patients must receive counseling from a Celgene REMS program certified pharmacy counselor
- Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist
 - Make sure form is signed and dated by the counselor and appropriate boxes are checked off
 - Keep a copy of the checklist and the associated prescription
- Please report adverse drug experiences that are suspected to be associated with the use of the drug and any suspected pregnancy occurring during the treatment

Steps for dispensing (continued)



Obtain confirmation number from Celgene

- Prior to each prescription, contact Celgene Customer Care at 1-888-423-5436, available 24 hours a day, 7 days a week. Eligible pharmacies may also use the Celgene REMS Pharmacy Portal at **www.CelgeneREMSPharmacyPortal.com**. Call your Celgene Account Manager to see if your pharmacy is eligible.
 1. Enter the pharmacy NABP number or DEA number
 2. Enter the authorization number written on the prescription
 3. Enter the number of capsules and milligram strength being dispensed
 4. Write the **confirmation number** and **date** on the prescription. Note: the confirmation number is **only valid for 24 hours**
- If you do not obtain a confirmation number, you are not permitted to dispense the product to the patient

If you have questions about the validity of the authorization or confirmation numbers, call Celgene Customer Care.

Steps for dispensing (continued)



Dispense prescription

- Include a Medication Guide with each prescription
- Document the dispense date on either the shipping receipt or pharmacy dispensing log
- Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
- For females of reproductive potential, product **must be shipped the same day** confirmation number is obtained **or handed to the patient within 24 hours**

Pharmacy staff knowledge check



- A confirmation number is valid for:
 - A. 24 hours
 - B. 7 days
 - C. 30 days

Correct Answer: A. 24 hours

- The confirmation number is **only valid for 24 hours**
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame

Pharmacy staff knowledge check (continued)



- Each prescription must have both an authorization number and a patient risk category written on it.
 - A. True
 - B. False

Correct Answer: A. True

- Only accept prescriptions with all of the following information:
 - Patient and prescriber demographics and contact information
 - Patient risk category
 - Dosing information and instructions
 - Authorization number
 - Prescriber signature

Pharmacy staff knowledge check (continued)



- The pharmacy must dispense no more than a 4-week (28-day) supply.
 - A. True
 - B. False

Correct Answer: A. True

- Dispense **no more than a 4-week (28-day) supply** with the Medication Guide
- A new prescription is required for further dispensing



THALOMID REMS™

Patient Resource Pack

THALOMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the *S.T.E.P.S.*® program)

The Patient Resource Pack contains:

- Patient Guide to THALOMID REMS™ Program
- Emergency Contraception Brochure
- Medication Guide

THALOMID is only available under a restricted distribution program, THALOMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.



THALOMID® is a registered trademark of Celgene Corporation.
THALOMID REMS™ is a trademark of Celgene Corporation.